IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

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IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	:	HON. DAN A. POLSTER
	:	MDL NO. 2804
	:	
APPLIES TO ALL CASES	:	NO.
	:	1:17-MD-2804

- HIGHLY CONFIDENTIAL -
SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

- - -

December 6, 2018

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Videotaped sworn deposition of RICHARD J. FANELLI, Ph.D., taken pursuant to notice, was held at DECHERT, LLP, 1095 6th Avenue, New York, New York, beginning at 9:09 a.m., on the abovedate, before Margaret M. Reihl, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

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THE VIDEOGRAPHER: We are now on the record. My name is Henry Marte, I'm a videographer with Golkow Litigation Services. Today's date is December 6, 2018, and the time is 9:09 a.m. This videotaped deposition is being held at 1095 Avenue of the Americas, New York, New York in the matter of National Prescription Opiate Litigation.

The deponent today is Richard Fanelli. All appearances will be noted on the stenographic record. The court reporter will now administer the oath to the witness.

... RICHARD J. FANELLI, PH.D., having been duly sworn as a witness, was examined and testified as follows:

MR. SNAPP: Before we get started, can I just confirm that everyone who is present either in person or on the phone agrees to be bound by the terms of the confidentiality protective orders either in the MDL or in the applicable state court

litigation. If that's not the case, please speak up now.

Hearing nothing, please proceed.

MS. DICKINSON: Thanks.

BY MS. DICKINSON:

Q. Dr. Fanelli, my name is Erin Dickinson.

We haven't met before today, correct?

A. Correct.

Q. Okay. I represent the plaintiffs in the piece of litigation that the court reporter just read off at the beginning of this deposition.

Do you understand that?

A. Yes.

Q. Okay. Have you ever been deposed before?

A. Yes.

Q. Okay. How many times?

A. Twice.

Q. Okay. And in what cases?

A. There were two patent litigation cases.

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Q. Okay. Do you recall roughly what years?
A. Probably within the last three years.
Q. And who is your current employer?
A. Purdue Pharma.
Q. Since you've been deposed on several different occasions, you may remember some of the basic rules, but I typically go over them at the beginning, just to make sure we understand each other, okay?
A. Yes.
Q. We have to give verbal answers to the questions so the court reporter can take them down.
Do you understand that?
A. Yes, I do.
Q. Nods of the head or uh-uhs or uh-huhs do not work, correct?
A. That's right.
Q. Okay.
A. I may do them but...
Q. We're not doing a great job so far, but we can't talk over each other as well.

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So if you will wait until I finish my question and you start your answer after that, I will try to do the same. I know it's very hard, okay?
A. Got it.
Q. If you at any point don't understand the questions I'm asking, please ask me to rephrase the question. I will assume if you answer that you've understood what I'm asking.
Is that fair?
A. Yes.
Q. Okay. All right. And we're going to have to do a little shuffling with the exhibits today. We're really far across the table from each other.
So we're going to hand you what's been marked as Exhibit 4 to your deposition.
(Document marked for identification as Exhibit Purdue-Fanelli-4.)
BY MS. DICKINSON:
Q. And I believe in Exhibit 4 is a copy of your CV; is that correct?
A. Yes.

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Q. Is that a current, accurate copy of your CV?
A. Yes.
MR. SNAPP: Do you have a copy for me?
THE WITNESS: I'm noticing --
MS. DICKINSON: Oh, here.
MR. SNAPP: Thanks.
THE WITNESS: I don't know if I updated my CV, but as of 2014, my title is now head of regulatory affairs.
BY MS. DICKINSON:
Q. Okay. Other than that change, does the work history summarized in this CV, Exhibit 4, accurately represent your employment history?
A. Yes.
Q. Okay. I'm going to hand you what's been marked as Exhibit 1.
(Document marked for identification as Exhibit Purdue-Fanelli-1.)
THE WITNESS: Do you need these back?

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BY MS. DICKINSON:
Q. You may keep those. Here come the copies.
A. That's for you.
Q. Okay. Dr. Fanelli, you understand you've been designated on behalf of several entities, Purdue Pharma, L.P., Purdue Pharma, Inc. and the Purdue Frederick Company to provide those corporations' testimony under Federal Rule of Civil Procedure 30(b)(6), correct?
A. Yes.
Q. Okay. And can we have an agreement today that when I use the term Purdue, that that references those three entities so I don't have to continually say the names of those companies over and over again; is that okay?
A. Yes.
Q. Okay. If one of your answers requires a specific response as to a specific company, certainly let me know, but we're just trying to make this a little cleaner and easier today; is that okay?
A. Yes.

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Q. Okay. You understand that the testimony you're going to give today is the testimony of those three corporate entities, Purdue Pharma, L.P., Purdue Pharma, Inc. and the Purdue Frederick Company, not testimony just based on your individual knowledge, correct?
A. Yes.
Q. You understand that the answers you're going to give today under oath will be binding on those three companies, correct?
A. Yes.
Q. All right. I've handed you what we've marked as Exhibit 1. That document is the Amended Notice of Deposition pursuant to Rule 30(b)(6) and document request pursuant to Rule 30(b)(2) and Rule 34 to defendants, Purdue Pharma, L.P., Purdue Pharma, Inc. and the Purdue Frederick Company.
Do you see that?
A. Yes.
Q. Okay. Were you provided with a copy of that notice that we've marked as Exhibit 1?
A. Yes.

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Q. When were you provided with that?
A. Prior -- I don't remember the exact date. It was several months ago when I met with the attorneys here from Dechert.
Q. And is it your understanding that you are being offered to provide Purdue's testimony on topics I have 7, 10, 30, 37, 38 and 44 of that notice? I'll get to --
A. Okay.
Q. -- the topic we talked about this morning in just a minute.
A. Yes.
Q. Okay. And prior to the deposition, counsel informed me that you had also been designated I think several weeks ago on topic --
MS. DICKINSON: Can you remind me, was it --
MR. SNAPP: Twenty-nine.
MS. DICKINSON: Twenty-nine.
BY MS. DICKINSON:
Q. Okay. Counsel and I had a discussion this morning that we would continue your 30(b)(6) testimony just on that particular

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topic till tomorrow.
MS. DICKINSON: And, counsel, is that our agreement?
MR. SNAPP: Yes.
BY MS. DICKINSON:
Q. Okay. Today we're going to cover topics 7, 10, 30, 37, 38 and 44 of the notice, okay?
A. Okay.
Q. Okay. And counsel also asked, for the record, if I would mark Purdue's supplemental responses and objections to the notice that is Exhibit 1. I have marked it as Exhibit 5 to your deposition, and we'll pass that to you now. I don't have copies of this.
(Document marked for identification as Exhibit Purdue-Fanelli-5)
BY MS. DICKINSON:
Q. Dr. Fanelli, is there anything today that would prevent you from giving accurate testimony?
A. No.
Q. Let's briefly, and I mean

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briefly, go through what you did to prepare for the testimony on these topics.
First, did you meet with counsel?
A. Yes.
Q. On how many times?
A. A handful. I wasn't counting. Under ten, I would think.
Q. And over the last several months?
A. Yes, started late summer, I think because my original deposition was scheduled prior to this date.
Q. Did you review any documents in preparation for your deposition?
A. Yes.
Q. Okay. Exhibit 1 has a schedule, Schedule B, and it's -- that Schedule B asks you to bring all documents which the deponent, that's you, has consulted or reviewed or plans to consult in preparation for his or her deposition and has relied upon or will rely upon for testimony on the above deposition topics.
Do you see that, Schedule B is on page 22 of Exhibit 1?
A. Sorry.

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Q. Take your time.
A. Yes.
Q. Okay. And have you brought those documents here today?
A. Yes.
(Document marked for identification as Exhibit Purdue-Fanelli-6.)
BY MS. DICKINSON:
Q. Okay. The record will reflect the witness brought several boxes of documents here today and they were provided to us this morning. We have marked those documents as Exhibit 6, and the court reporter will copy those documents that Dr. Fanelli brought with him today as Exhibit 6.
Generally, what are -- what is in that file that you brought with you today?
A. Documents that I looked at when meeting with the attorneys. It lists that are related to these 30(b)(6) topics.
MR. SNAPP: I'm sorry to interrupt. I heard someone beep in. Did someone join on the phone?

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BY MS. DICKINSON:
Q. And are there any documents that you reviewed or relied upon in getting ready for your testimony today that are not included in Exhibit 6?
A. No.
Q. If at any time during your testimony you need to refer to documents in that box, will you please let me know what it is you are referring to so the record could show what we're looking at; is that fair?
A. Yes.
Q. All right. We discussed a few minutes ago that you're here to testify on behalf of Purdue on certain topics. I think we're going to start and just go through those topics, and that's what we're going to do for the balance of today.
The first one that you've been identified to testify about is topic 7. Could you turn to that topic, or if you have a list of the topics, that's fine.
A. I have.
Q. And I'm just going to read in for the record the language of that topic that you will be providing testimony on.
Topic 7 says, the identity of all persons who were responsible for testing the safety and efficacy of opioid products for long-term use or for chronic pain, or who received reports, test results, studies or any other documentation regarding the testing of safety and efficacy of opioid products for long-term use or chronic pain -- I'm sorry -- for chronic pain or long-term use and the results of any such testing.
Have I now read that accurately, with the last mistake there at the end?
MR. SNAPP: Just to clarify, I don't want to interrupt, but our objections that we marked as Deposition Exhibit 5 used slightly different language in our response and our designation of Dr. Fanelli, so he's prepared to testify consistent with the language that's included in our supplemental responses and objections that have been marked as Deposition

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Exhibit 5.
MS. DICKINSON: Okay.
BY MS. DICKINSON:
Q. So, Dr. Fanelli, you are not here today prepared to testify on topic 7 as written; is that correct?
A. It's -- yes, it's slightly modified.
MS. DICKINSON: I'm probably going to need the copy of your objections back, since we only have one.
And, for the record, counsel stated that Dr. Fanelli is not here prepared to testify on topic 7 as written, but that he is here prepared to testify on topic 7 as rewritten in response to topic number 7 contained in Exhibit -- is it 5? Five, that were served on November 15th, 2018.
That response reads, Purdue designates Richard Fanelli, Ph.D. to provide testimony regarding the identity of those responsible for, or who received reports, test results, studies

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or other documentation regarding the testing of the safety and efficacy of OxyContin, Hysingla and Butrans for long-term use or for chronic pain.

Counsel, could you please summarize what the limitation that you're placing on his testimony of topic 7 is, please.

MR. SNAPP: I'm not putting any limitation other than what's included in our objections that are marked as Deposition Exhibit 5, so he's prepared to testify on topic 7 as well as topics 10, 29, 30, 37, 38 and 44 as worded in our supplemental responses and objections served on November 15th that have been marked as Deposition Exhibit 5.

MS. DICKINSON: But he is not here prepared to testify on topic number 7 as written in the amended notice marked as Exhibit 1, correct?

MR. SNAPP: He's here to testify consistent with Exhibit 5.

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MS. DICKINSON: Well, I think we'll start asking questions, and where he's not prepared, you can let me know. It's the best way I can think to go about this. We may have to come back, but we'll try.

BY MS. DICKINSON:

Q. Dr. Fanelli, we're going to start with topic 7. We're going to try to break it up in pieces, so it's a long topic and it has varying subparts. If you're not prepared to testify about a certain subpart, then you can let me know, okay?

A. Yes.

Q. Let's talk about a couple preliminary matters related to this particular topic.

Would you agree with me that a pharmaceutical company like Purdue has a responsibility to ensure the safety and efficacy of the drugs that they sell?

A. Yes.

Q. Would you agree with me that a pharmaceutical company like Purdue who markets

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and sells a drug has the primary responsibility to ensure that the drugs that they are selling are safe and efficacious?

A. The pharmaceutical company presents evidence of the safety and efficacy of its products that the FDA evaluates in a benefit-risk assessment in the approval of the product.

Q. I'm asking a little different question.

I understand the FDA exists, but I'm asking does a pharmaceutical company who intends to market and sell a drug, does that company bear the primary responsibility of ensuring that a drug is safe and efficacious?

MR. SNAPP: Object to the form, scope.

THE WITNESS: The pharmaceutical company's responsibility is to provide the evidence, investigate of their products.

BY MS. DICKINSON:

Q. Do you disagree that the pharmaceutical company like Purdue who markets

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and sells a drug has the primary responsibility for its safety and efficacy?

MR. SNAPP: Object to the form. Beyond the scope.

THE WITNESS: Could you repeat the question. Sorry.

BY MS. DICKINSON:

Q. I'm trying to get at who has the ultimate responsibility for the safety and efficacy of the drugs that Purdue is selling?

MR. SNAPP: Object to the form.

THE WITNESS: I would -- yes, the pharmaceutical company is responsible for demonstrating the safety and efficacy.

BY MS. DICKINSON:

Q. Let's turn to topic 7, and I'm going to turn to topic 7 in the notice marked as Exhibit 1 so we're consistent here.

In topic 7 there are some capitalized terms, opioid and opioid products.

Did you see that?

A. Yes, I see it.

Q. Okay. And do you understand what

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the definition of the capitalized term opioid products in that topic is asking about?
A. Yes.
Q. Okay. And what are those products?
A. Opioid products are products that contain opiate pharmaceutical agent.
Q. I'm sorry, I wasn't very clear. For the purpose of this topic, opioid products is a capitalized term and has a definition contained in this notice and lists what we're talking about here.
Were you provided by counsel or did you come to understand what that defined term means when we're asking about that in this topic?
A. Yes.
Q. Okay. And what are the drugs we're talking about with respect to this topic?
MR. SNAPP: I'm sorry. Just so the record is clear, do you want him to look at the opioid products definition on page 3 of the document?
MS. DICKINSON: Well, I assume

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he's here prepared to answer the question, so I was trying to make it a little easier.
BY MS. DICKINSON:
Q. If you have an understanding of what products we're talking about today, that would be helpful for you to give it to me; otherwise, we can go back and read the definitions.
A. I'd like to go back and look at the definition.
Q. Okay. All right. So let's turn to page 3. I'm sorry, that's not correct. Definitions are starting at Schedule A and paragraphs 15 and 16.
Do you see that?
A. Yes.
Q. Okay. And there is in paragraph 15 a definition of opioid, correct?
A. Yes.
Q. In paragraph 16 there's a definition of opioid products, and that definition for the purpose of this notice refers to the opioids that you, that means Purdue,

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sold, promoted, marketed, manufactured, or distributed. This includes coatings, capsule configurations, delivery systems or mechanisms that include but are not limited to anti-abuse, tamper resistance and crush-proof mechanisms and mechanisms to deter immediate release. Opioid products is also intended to include rescue medication for break through pain.
Have I read that correctly?
A. Correct.
Q. And the definition in 16 refers to opioids as a capitalized term, correct?
A. Yes.
Q. So that capitalized term is defined in 15, correct?
A. Yes.
Q. And in that term "opioid refers to that class of drugs, legal or illegal, natural or synthetic, used to control pain, including, but not limited to, the drugs referenced in Plaintiffs' Complaints in the above-referenced matter."
Do you see that?
A. Yes.

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Q. Okay. And were you provided with the list of the drugs that Purdue marketed and sold that are contained in the Complaint referenced in the above-referenced matter?
A. Yes.
Q. Okay. And what are those drugs?
A. OxyContin, Butrans and Hysingla.
Q. Okay. I'm going to hand you what has been marked as Exhibit 7.
(Document marked for identification as Exhibit Purdue-Fanelli-7.)
BY MS. DICKINSON:
Q. Dr. Fanelli, I'll represent to you that Exhibit 7 is the Second Amended Corrected Complaint filed in this matter.
Do you see that?
A. Yes.
Q. And let's turn to, if you would, paragraph 40.
Do you see that?
A. Yes.
Q. Okay. And in paragraph 40 the drugs that are listed for Purdue in the Amended

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Complaint are OxyContin, MS Contin, Dilaudid, Dilaudid HP, Butrans, Hysingla ER and Targiniq ER.

Do you see that?

A. Yes.

Q. Okay. Are you prepared to offer testimony on these topics on all of those drugs?

A. Yes.

Q. Let's talk briefly about when each of those drugs were sold. MS Contin was sold from 1987 to roughly what date?

MR. SNAPP: Objection, beyond the scope.

Go ahead.

BY MS. DICKINSON:

Q. Go ahead.

A. MS Contin is currently being marketed.

Q. So 1987 to present would be accurate?

A. I'm not a -- I'm not exactly sure of the launch date of the product.

Q. Do you know roughly the dates OxyContin has been sold?

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A. It was approved in '95 and continues to be sold, a reformulated version of OxyContin.

Q. Butrans was sold from roughly 2010 to present; is that correct?

A. Correct.

Q. Do you know roughly the years Dilaudid was sold by Purdue?

A. I don't remember -- Purdue end licensed Dilaudid from Abbott, I believe, and I don't remember the years.

Q. Would 1984 to present sound reasonable to you?

MR. SNAPP: Object to the form.

THE WITNESS: I don't remember the date it started.

BY MS. DICKINSON:

Q. What about Hysingla, when has Hysingla been sold and marketed by Purdue?

A. Hysingla is currently continues to be sold. I don't remember the approval date.

Q. I have 2014.

Does that sound accurate to you?

A. It does.

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Q. I also have 2014 to present as the dates that Targiniq was sold.

Does that sound accurate?

A. That is not accurate.

Q. Okay. How is it -- what dates was that product sold between?

A. Targiniq has not been commercialized or sold.

Q. So today, just to make it easier, when I'm asking you about a particular drug, let's take OxyContin, unless I specify otherwise, you know, by giving you a date, I'm asking you for your answer regarding the entire time period for that drug.

Does that make sense?

A. Yes.

Q. Okay. And can we agree that's what I'm asking unless I ask you about specific years or dates?

A. Yes.

Q. Okay. All right. Let's talk about -- we're going to break this up in pieces, topic 7. Part of topic 7 asked you to identify all persons who were responsible for the testing

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for safety and efficacy of these drugs we just talked about, correct?

A. Yes.

Q. Okay. Who -- who are the persons -- and let's talk about this, I want this to be as efficient as possible. We could start at the department level, if that makes sense. If it's literally a person or persons, you can let me know, but let's start with the departments that are responsible for the testing regarding safety and efficacy, and we'll just run through each of the drugs.

Is that okay?

A. Sure.

Q. Okay. So who was responsible for the testing of the safety and efficacy for MS Contin?

MR. SNAPP: Object to the form.

THE WITNESS: What would be helpful is to refer to the org charts that we presented.

BY MS. DICKINSON:

Q. Sure.

A. And especially around

departments. As you stated, there's a long, you know, period of time and individuals and departments varied over the history, and I think that would be helpful.

Q. Absolutely, if you need to refer to a document, let's look.

MR. SNAPP: So what time period do you want him to ask -- answer the question for?

MS. DICKINSON: I'm asking for the entire time period for MS Contin who was responsible, what department for the safety -- the testing for safety and efficacy for that product.

MR. SNAPP: So do you want him to start with the '95 --

THE WITNESS: When it was approved --

MR. SNAPP: -- org charts and work all the way through the 2017 org charts?

MS. DICKINSON: Sure. I mean, I'm just asking for the answer. I don't know what I want him to look at. He's

the one that looked at the documents.

BY MS. DICKINSON:

Q. I don't know what you need to look at.

MR. SNAPP: Well, to be fair, he wasn't designated to testify on MS Contin. He testified earlier that he's prepared to do it, but he was not designated to testify on MS Contin.

MS. DICKINSON: So are you going to provide a different witness to testify on that part of the topic?

MR. SNAPP: No, we're standing by our objections.

MS. DICKINSON: So he's not going to answer the question -- any questions today on any of these topics with respect to MS Contin?

MR. SNAPP: I didn't say that. He told -- he testified earlier that he's prepared to testify on those topics. I'm saying that it's beyond the scope of the designated -- his designation so --

MS. DICKINSON: Then we'll move on.

MR. SNAPP: If you want him to testify on it, he can go through each of the org charts, that's fine. Do you want him to start with '95?

BY MS. DICKINSON:

Q. Dr. Fanelli, can I ask you just a question, is the -- are the departments responsible going to change if -- by drug?

A. Generally not.

Q. Okay. Because that may make it faster, because we have a number of drugs here, ones we read off a few minutes ago that were in the Complaint, right, and if the answer is that the same departments and people were generally responsible for the testing regarding safety and efficacy, I don't want to have to go through each, if that's possible.

Is that fair?

A. Yes.

Q. Okay. So why don't we try to do this generally with respect to the drugs that we listed in the Complaint, and if there is a time

when the responsibility lies outside of that department you were describing, could you let me know?

A. Yes.

Q. Okay. Let's try that. Okay. So let's start in 1995. What were the departments that were responsible for the testing of the safety and efficacy of Purdue's opioid products at that time?

A. Do you have --

Q. I don't have, but I think I'm about to get a copy of whatever it is you're looking at.

A. So if we -- can I refer to the index of this is the org chart from 1995.

Q. Can I hand you an exhibit sticker, please, to put on that document you're looking at?

MR. SNAPP: What exhibit number is this?

MS. DICKINSON: I just handed you or you handed me but now we've marked a document as Exhibit 8.

(Document marked for

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identification as Exhibit Purdue-Fanelli-8.)
BY MS. DICKINSON:
Q. And what is this document?
A. This is an org chart from Purdue, the Purdue Frederick Company from June of 1995.
Q. Okay. And we were talking about the departments in 1995 who were responsible for the testing for the safety and efficacy of Purdue's opioid products. So starting in 1995, what were those departments?
A. So the safety and efficacy, so that includes both -- the majority of that, those individuals were in the research and development department and the -- if you look under -- I was referring to the index.
Q. Okay.
A. All in the scientific and medical affairs grouping. So the clinical research group would be the ones designing the clinical trials. Research and development are related to early development of products, so the -- from all the way from testing in nonhuman subjects, animal studies all the way through -- all the

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way through the beginning of testing in humans. That includes things like formulation, development and so forth.
There's biostatistics and clinical data management individuals. Clinical research would be running those trials, and the group, the biostatistics would be analyzing those trials and reporting on them.
And then regulatory affairs and compliance while not conducting those -- you were asking about conducting, so they wouldn't be doing the trials, so I guess it would reside in those departments.
Q. What was the -- what is the responsibility of the regulatory affairs department with respect to clinical trials?
A. Just clinical trials? So --
Q. I'm sorry, with respect to testing or studies or clinical trials, I'm talking pretty broadly here.
A. Sure. So testing -- prior to testing in humans, so in animal studies, lab in vitro studies and so forth, there's not much oversight in regulatory affairs, although

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regulatory affairs would be involved in team meetings and designing and looking at those trials. Regulatory affairs gets involved once the studies are in humans, so in a more direct way, because those studies cannot be conducted without an investigational new drug application in effect with the FDA, those are required.
So all of the protocols and so -- and information, including the nonclinical information, is submitted to FDA prior to those studies and all the protocols, so that's when regulatory -- the bulk of regulatory's involvement in that testing occurs.
In the compliance group it varies over -- this is -- you asked about throughout time and studies, at this time a compliance group resided within regulatory affairs, it no longer does, but that group is -- does auditing of results but also monitors clinical trials for conduct.
Q. Okay.
A. I think that's -- yeah, on this sheet. Do you want to --
Q. Are there any other departments

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who have responsibility for the testing of the safety and efficacy of opioid products other than those we just talked about under scientific and medical affairs at this point in time?
MR. SNAPP: Object to the form.
BY MS. DICKINSON:
Q. 1995.
A. I was going to ask what do you mean by "responsibility"?
Q. I'm just trying to find out who had involvement. So the topic basically -- and I'll tell you where I'm going with this, if it will make it easier.
We want to know the persons -- and by persons we can start with departments and we can talk about how many people are in those departments, that had involvement with the testing for the safety and efficacy of Purdue's opioid products. That's just what we want to find out is who at the company was involved in that subject area.
A. Understand.
Q. So we know that the folks in scientific and medical affairs were, and all I

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want to know is are there other departments at this time in 1995 that would have been involved in that subject area?

A. So there are individuals and executive -- I have to look at the chart. I joined in 2000, but I -- so I have understanding, though. There may have been some executives who would not conduct or design but might be involved in oversight or making decisions, for instance, on direction of plan and so forth.

Q. And who would those executives be?

A. So let me look at -- there -- they would be heads of the departments. There's an executive committee. I don't remember back in '95, but I know when I joined it was in existence, that included the heads of all the departments, the vice presidents that are listed there.

Q. And when you say "there," where are we looking?

A. I'm sorry, on page -- doesn't have a page number. It's the third page.

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Q. Okay. Third page that's got a number at the bottom --

A. Actually, sorry.

Q. Okay. Go ahead.

A. The -- if you look at the -- yes, I'm sorry, yeah, I see the numbers now. There's three different numbers.

Q. We can pick one.

A. Pick the bottom one. The bottom one that starts with PKY.

Q. Sure.

A. The last three numbers are 594.

Q. Okay. And, for the record, you're looking at PKY181872594?

A. Correct.

Q. And I'm sorry, your answer was that some of the individuals on this page may also had involvement in the testing for the safety and efficacy of Purdue's opioid products in some way?

A. Not in the testing. So if we're restricting to that, they wouldn't have done any testing.

Q. Did they receive results of

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testing?

A. In instances where programs were being assessed or decisions, high level decisions, in other words, go, no go decisions were made, they might have received summaries of results.

Q. When you're talking about go, no go decisions, are you talking about product-based decisions or test-based decisions?

A. Product-based decisions.

Q. And --

A. For this level.

Q. Who on this list on the page we were just talking about that ends in 594 would have been involved in those types of decisions?

A. I'm not aware of the specifics during this time period.

Q. Okay. What do you mean by "this time period"?

A. In 1995.

Q. Okay. You haven't prepared or asked anyone in preparation for your deposition about the time period 1995 to when you arrived in 2000?

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MR. SNAPP: Object to the form.

THE WITNESS: Just this -- on this particular issue, I didn't ask.

BY MS. DICKINSON:

Q. Okay. Other than some of the individuals on this page, 594, may have had involvement with regarding testing as to safety and efficacy and the department we talked about, the scientific and medical affairs department.

In the time period 1995, were there other departments at Purdue that had involvement with testing for safety and efficacy of Purdue's opioid products?

A. Not that I'm aware of.

Q. Okay. Your answers about the 1995 time period, how long were the departments you identified responsible for the testing regarding safety and efficacy? I'm just trying to figure out where we're going next.

A. So those departments or functions were responsible throughout. So they may be -- the example I gave was compliance is no longer in regulatory affairs; however, they're still involved, but they're under drug safe -- a

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different department. So those functions are -- continue to be involved.
Q. Got it.
How -- do you know how many people in the scientific and medical affairs department were involved in the testing for the safety and efficacy of Purdue's opioid products?
MR. SNAPP: Object to the form.
THE WITNESS: We could look at the -- these org charts. As I said, it varied over time, but I don't have a number in mind.
BY MS. DICKINSON:
Q. So when we're trying to identify all the persons who were responsible for testing for the safety and efficacy of those products, we can't identify those persons?
A. We can from these org charts if you want to look.
Q. Okay. Let's do our best to try and do that. Okay.
So to back up a minute, you said from 1995 throughout the time period, do you mean 1995 to present where these functions

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generally were the ones that touched safety and efficacy testing; is that right?
A. Yes, correct.
Q. Okay. They may have moved -- for example, compliance may have moved outside of scientific and medical affairs, but compliance still did touch upon safety and efficacy testing; is that right?
A. Correct.
Q. Okay. Let's then go to -- you said you had to refer to some other org charts to tell me where the actual positions or persons would reside that -- that were responsible for testing of safety and efficacy, right?
A. Correct.
Q. Okay. Where do we look?
A. Can I ask, can we look at an org chart from when I joined Purdue or shortly thereafter? Those individuals -- I mean, I know many of these, but I'd be much more familiar and be able to answer directly.
Q. Sure, yeah, absolutely.
A. So perhaps 2002, something. Is that all right?

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MS. CLARK: How about 2001 or 2004?
THE WITNESS: 2004.
MR. SNAPP: Erin, would you like to mark this?
MS. DICKINSON: Yes, please. And I'll need a copy as well, if you don't mind.
(Document marked for identification as Exhibit Purdue-Fanelli-9.)
BY MS. DICKINSON:
Q. Dr. Fanelli, can I ask you a quick question before we move on to what we've just marked as Exhibit 9. Can I ask you a question about Exhibit 8, the one we were just looking at, the early 1995 organizational chart?
A. Yes.
Q. Okay. Where do I find the corporate structure of the scientific and medical affairs division on that org chart? It appears to me to be page ending in 566, but am I right about that?
MR. SNAPP: I think you switched

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sets of Bates numbers.
MS. DICKINSON: Oh, I'm sorry.
THE WITNESS: Yes.
BY MS. DICKINSON:
Q. The set ending in 601.
A. Yes.
Q. Okay. For the record, we're looking at PKY181872601; is that right?
A. Correct. And...
Q. Okay. And that page depicts the individuals in the scientific and medical affairs group at Purdue Pharma back in 1995; is that right?
A. Yes.
Q. Okay. Are there any other individuals that were in that division at that time at Purdue that would not be depicted on this page?
A. Yes. If you -- on subsequent pages there's drill down to -- if you look at the header -- let's take the example of Robert Kaiko on the far left there. If you look on the next page, there's individuals under Robert Kaiko, clinical research, that those individuals

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are in his -- and there are subsequent pages where those are described.
Q. Okay. And so we're clear, it looks like all subsequent pages in this org chart following the page that ends in 601 are individuals in the scientific and medical affairs group; is that right?
A. I'll have to check each page. Yes.
Q. Okay. So if I wanted to find all of the persons that touched the safety and efficacy testing for the opioid products, these pages from PKY181872601 through the page that ends in 608, that's where I find the totality of those individuals; is that right?
A. Correct.
Q. Okay.
A. Now, some of the individuals, administrative assistants, you know, wouldn't have done testing, of course, and so forth.
Q. But it's not more than the individuals --
A. Correct.
Q. -- listed in here, correct?

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A. Right. It's a sub --
Q. Okay. Might be less?
A. Correct.
Q. Okay. So if I wanted to know how many folks at Purdue in the 1995 time period spent time on testing for safety and efficacy, it would be -- I could add up the folks on these pages and it would be some number less than that; is that accurate?
A. That's accurate.
Q. Okay. All right. Do you know how long the organizational structure that is listed in Exhibit 8 was in place? I'm trying to figure out where the next point in time was that the medical affairs department, for example, would have changed?
A. I would -- I don't know when it changed.
Q. Okay. Let's look at Exhibit 9, and let's do the same thing for Exhibit 9, if you would, in telling me what departments at Purdue in this time period and it looks like this time period, this is a chart from August of 2004; is that right?

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A. Yes, correct.
Q. Okay. And, if you would, tell me the departments at this time that were responsible for testing for safety and efficacy of Purdue's opioid products.
A. So, sorry, I'm trying to locate.
Q. No, that's okay.
A. This one doesn't have a table of contents.
There's an R&D -- so if I just look at the -- what's the number at the bottom? It ends in 807, so the second page.
Q. Okay. And, for the record, we're looking at the Bates number PURCHI003290807, correct?
A. Correct.
Q. Okay.
A. So if you look, individuals reporting up to the chief executive officer, Michael Friedman at the time, Fred Sexton's department, technical operations would be involved. Those folks do some of the testing around formulations and so forth. And the -- it says vacant at this time, executive vice

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president, worldwide R&D and chief scientific officer would be responsible for the other -- the clinical and so forth.
And then the regulatory at this time were they in -- I believe we can look further, but I think they were in that department as well.
Q. Okay. Can I ask you, this document is 2004.
A. Mm-hmm.
Q. You got to the company in 2000; is that right?
A. Correct.
Q. Was the basic organizational structure from 2000 to 2004 similar to what we're looking at on this page that ends in 807?
A. Yes.
Q. Okay.
A. Right.
Q. So when I'm asking you questions about the departments that had responsibility for testing for safety and efficacy, that would be true from at least 2000 to at what point in time?

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A. Around this time. I believe shortly after this, there was -- there were some changes.
Q. Okay. So from 2000 to roughly mid-2004, your answers will be the same, correct?
A. Yes.
Q. Okay. And you've identified the R&D department and technical operations as the two departments that would have been involved in that, correct?
A. Yes, right.
Q. Previously medical affairs had been the department that oversaw testing for safety and efficacy, correct? Scientific and medical affairs, correct?
A. Yes, I knew there was another term, yeah.
Q. And previous to the 2000 time frame, Paul Goldenheim had headed up that division, scientific and medical affairs; is that right?
A. Correct.
Q. Is he still with the company?

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A. No.
Q. When did he leave?
A. I believe it was around 2007 or -- I don't have an exact date.
Q. Okay. This org chart says that the executive vice president in charge of research and development and the chief scientific officer position was vacant as of 2004, but between 2000 and 2004, generally, who sat in that seat?
A. That would have been Paul Goldenheim.
Q. Okay. Essentially, did the medical -- or the scientific and medical affairs division get renamed as research and development; is that fair to say?
A. I would -- I would characterize it as the departments were -- became independent, not independent, but separate departments.
Research and development and medical affairs and as we -- for instance, today, that we have R&D is one group, medical affairs, both reporting in to -- to the

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executive department, group.
Q. Okay. And at this point in time between 2000 and 2004, medical affairs no longer had involvement in the clinical -- or in the testing for safety and efficacy of opioid products; is that true?
A. I'm sorry, can you -- what time period?
Q. The 2000 to 2004 time frame that we're looking at an org chart that would represent the structure in that time period.
A. Those responsibilities rely -- lie in the R&D part of it. Medical affairs depends on, you know, as I say, they move -- if you take the medical affairs function, they're responsible for post approval, scientific and communica -- and those kinds of functions. So testing for medical affairs is along those time frame, so after approval of a product.
Q. Where do I find the medical affairs division in this org chart?
A. I think if you -- sorry, let me -- there it is. Should I read you the number?

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Q. Yes, please.
A. Can I read you the last three, or do you want --
Q. Last three is fine.
A. Okay. 821.
Q. Okay. And we're looking at the page that ends in 821 contained in Exhibit 9, and that would be a depiction of all the individuals in the medical affairs department; is that what you're telling me?
A. Correct. It includes both medical affairs and pharmacovigilance or drug safety as well.
Q. And those folks would have involvement with safety and efficacy testing, it would just be post product approval, correct?
A. I wouldn't characterize -- they're more on the safety side. They could conduct efficacy trials, but those are generally conducted prior to approval, but there are cases where if it's related to a new indication or demonstration, it could -- it could go both R&D and medical affairs at that time period.
Q. Okay. Where do I find the R&D

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piece of the individuals in this org chart that worked in R&D?
A. Looking for that. Part of it is -- let me look at this. Bates number or whatever that, ends in 827.
Q. Okay.
A. There are -- it lists folks, I can't read the dark print there, but those are some of the folks who did the early testing, animal testing, says toxicologists and some of the project managers, I talked about that department being involved, they organize the department, so that's part of it.
MR. SNAPP: Erin, we've been going an hour, can we take a couple minutes break.
MS. DICKINSON: Yeah, let's just finish this up quickly.
THE WITNESS: Sure. I don't see on this particular grouping the drill down to those other individuals.
BY MS. DICKINSON:
Q. You mean you don't see the individual drilled down on the research and

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development department?
A. Correct.
Q. Okay. Where would I go to find out in the time period 2000 to 2004 who was in the research and development department that was responsible for safety or efficacy testing regarding opioid products?
A. Perhaps I think the best would be to look at a different org chart.
Q. Okay.
MS. DICKINSON: Why don't we take a break there.
THE WITNESS: Okay.
THE VIDEOGRAPHER: Stand by, please. Remove your microphone. Okay. The time is 10:12 a.m. going off the record.
(Brief recess.)
THE VIDEOGRAPHER: Okay. We are back on the record. The time is 10:20 a.m.
BY MS. DICKINSON:
Q. Dr. Fanelli, we're back on the record after a short break.

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I want to just see if we can round out this topic in a little bit more efficient way since we've taken a break. We were going through the departments that had responsibility for safety and efficacy testing, and I understood your testimony this morning to say that generally medical affairs and research and development were the departments that those responsibilities would lie within over the entire period of time; is that accurate?
A. Yes.
Q. Okay. Can we talk about who headed up those two departments over time, and maybe we can be done with it then.
A. Okay.
Q. I assume then I can find the individuals that worked within those departments within the org charts that you've brought with you today; is that right?
A. Generally. Like I said, it may -- it depends on which one, how far down they drilled into the individuals. We have a good example that was more complete in -- what was it, 2000 and --

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MR. SNAPP: One.
THE WITNESS: 2001 you can see that, that gives you a good representation of those individuals.
BY MS. DICKINSON:
Q. Okay.
A. Yeah.
Q. And we talked about that Mr. Goldenheim headed up the scientific and medical affairs division from roughly 1995 to 2000; is that right?
A. I believe that's correct.
Q. Okay. And you thought that he likely headed up the R&D department in the years roughly 2000 to 2004 time period; is that correct?
A. I believe that's correct.
Q. Okay. We know that the seat was vacant in 2004.
A. Right.
Q. But then who is the person that headed up the R&D department going forward after 2004?
A. I'd have to look at the next one.

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Q. Okay.
A. And I can --
Q. Let's see if we can quickly do that.
A. Yeah, yeah.
I have -- is it okay? So I'm looking at -- and this is a good example of what I was talking about before, the organization chart from January of 2007.
MS. DICKINSON: I ask you to give him that exhibit sticker.
BY MS. DICKINSON:
Q. We're going to mark as Exhibit 10 the organizational chart for Purdue for January 2007; is that accurate?
A. Correct.
(Document marked for identification as Exhibit Purdue-Fanelli-10.)
BY MS. DICKINSON:
Q. And that is a true and accurate copy of Purdue's organizational chart dated January 2007?
A. Yes.

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Q. And who at that time period sat at the head of both medical research and R&D?
A. If you look at -- there's no number -- oh, yeah, there is, sorry. The second page, 144 on the bottom.
Q. Mm-hmm.
A. This is reporting in to Michael Friedman at the time, and it's a good example of how things change and but where the responsibilities still lie. If you look on the left side, four down is medical research, so it's now -- now at this current time research and development is split into two groups at least, maybe three, at least on that org chart. You see Craig Landau who is our current CEO, at this time was the vice president of medical research, so those are the individuals who conducted the clinical trials.
If you look on the right, almost right across from that but a little up, it's Robert Kaiko. He's the vice president of R&D portfolio development, so that would be the folks before the clinical development that we talked about earlier, so lab testing, animal

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testing. So during this time period, those are the two groups doing the primary -- or responsible for the scientific preclinical and clinical testing.
As I mentioned, regulatory affairs is involved to a certain extent, not in the testing, of course, but in reporting or providing guidance, and that's headed by Tony Santopolo down there.
And, again, Fred Sexton's department, which I mentioned before, technical, at this point that's -- we talked about that very -- just formulation, so those individuals might be doing some formulation testing.
Q. Okay. And all of those divisions reported generally to the president and CEO at that time, Michael Friedman; is that correct?
A. Correct.
Q. And the org charts we took a look at earlier, those positions also reported to the president and CEO, who in between '95 and what we're looking at here in '07, was Michael Friedman; is that right?
A. Not in '95. I don't remember --

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Q. Okay.
A. -- but it's on the org charts is my understanding.
Q. Okay. What -- we're up to 2007.
A. Yep.
Q. I want to know who headed the divisions that had responsibility for safety and efficacy testing or had involvement in that from '07 to present. What's the next document we need to look at to talk about that?
A. I don't remember when it changed again. What's the next one you have?
MR. SNAPP: 2010.
THE WITNESS: I'm consulting '10 to see if it's different, and I'll let you know.
BY MS. DICKINSON:
Q. Okay.
A. This is in January of 2010, it's relatively similar. I mean, medical research now has clinical, medical and regulatory, all together. Sorry.
(Document marked for identification as Exhibit

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Purdue-Fanelli-11.)
BY MS. DICKINSON:
Q. I'm going to hand you what's an exhibit sticker, we're going to mark that as Exhibit 11, and what is Exhibit 11?
A. It's the organization chart from January of 2010.
Q. Okay. And at that point in time, what were the divisions that were responsible for the testing of safety and efficacy of Purdue's opioid products, and who headed those divisions?
A. So if you look on the -- sorry. 457, last three numbers, Craig Landau was still vice president, head of medical research, but under his department medical and regulatory have now been joined, so they're under -- in that department.
And there's an open position, I'm not sure what that is at the time. It's a vice president of R&D. So in that group is the R&D group that would have been -- it doesn't have a name assigned to it at the time.
Here we go. I just want to see

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if I was on the org chart. I don't see --
MR. SNAPP: Is there another question? I think he answered the question.
MS. DICKINSON: I don't know. I thought you were looking for something.
MR. SNAPP: The divisions and who headed the divisions.
THE WITNESS: Yeah, I don't see the breakouts all the way down, but that's the department.
BY MS. DICKINSON:
Q. That's 2010?
A. Yes.
Q. What do we need to look at to take us through the present on who was responsible for the testing and safe -- of safety and efficacy for your opioid products?
A. I can tell you today, and I think it's been this way -- I can't remember when it became, but it's been for a number of years, there's a vice president of R&D, so the research and development department, and that includes at the current time all the clinical research,

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preclinical research down to the bench, analytical testing is all in that R&D department.
And the medical affairs department is separate and as we talked about the difference between those two responsibilities.
Now, testing -- statistics, that group is also in R&D currently, and I think you'll find all the individuals there.
Q. Who has headed R&D from roughly 2010 to present?
A. Currently, it's John Ringer is the head of R&D for the last -- I think it's been a year and a half or so.
Prior to that it was Gary Styles, I think Gary Styles. I'd have to look.
And prior to that it was Todd Baumgartner, anyway.
And then I think we're -- I can't remember where we left off going the other way.
Q. That's okay. Who has headed medical affairs from roughly 2010 to 2017 -- or I'm sorry -- to present?

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A. Currently head of medical affairs is Marcelo Bigal is his name, he's recently a recent hire.
Prior to Marcelo, Monica Kwarcinski was the head for the interim period.
Prior to that it was Gail Cawkwell was the head of medical affairs.
Robert Reeder was way back, I can't remember if there were folks in between. I'd have to look at the charts.
Q. Okay.
A. But those are representative.
Q. And all of the org charts you've reviewed in getting ready for your testimony are in the boxes we marked as Exhibit 6 at the beginning of the day; is that right?
A. Correct.
Q. Okay. All right. Let's move on from this subject.
We're going to talk about the rest of the parts of the topic 7 that we have here, because one part was the identity of the persons who were responsible for the testing, but also who received the reports and the

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testing and the results of those reports, right?
A. Correct.
Q. Okay. So we're going to move on to that second part. We've talked about the people who were responsible. Now we're going to kind of move on, but we're still on topic 7.
Let's talk about 1996 and OxyContin. 1996 OxyContin had been approved, correct?
A. Yes, the original formulation.
Q. Correct, the original formulation of OxyContin had been approved by the FDA; is that right, in 1996?
A. '95.
Q. Correct, okay.
And I'm going to hand you what has been marked as Exhibit 12.
(Document marked for identification as Exhibit Purdue-Fanelli-12.)
BY MS. DICKINSON:
Q. And that is a document that was produced to us by Purdue in this litigation beginning with the Bates number -- when I say

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"Bates number," the number at the bottom, PKY183226682.
That is -- does this appear to be a true and accurate copy of the label, the original label for OxyContin?
A. Just checking the date.
Q. Sure.
A. Yes, it does.
Q. Okay. And then let's turn to the page that ends in 87 in the middle of Exhibit 12. Tell me when you're there.
A. Okay, I'm there.
Q. Okay. And in the middle of that page, there is a section called "Drug Abuse and Dependence" and in parentheses "Addiction."
Do you see that?
A. Yes.
Q. Okay. And in the first paragraph of that section, the last sentence has a sentence that reads, "Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug."
Have I read that correctly?
A. Yes.

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Q. Okay. And that sentence appears in the label that Purdue had negotiated with the FDA in 1995 or beforehand; is that right?
A. Yes, this is the approved version by FDA, FDA's approval, yes.
Q. Okay. And one of Purdue's messages in marketing was the message that because of the extended-release formulation that OxyContin had less abuse potential than other pain medications, correct?
MR. SNAPP: Objection, beyond the scope.
BY MS. DICKINSON:
Q. Correct?
MR. SNAPP: Same objection.
BY MS. DICKINSON:
Q. You can answer.
A. Could you repeat the question.
Q. Sure. And one of Purdue's messages in marketing was that because of the extended-release formulation of OxyContin, that OxyContin had less abuse potential than other pain medications, correct; that was one of the marketing messages for OxyContin?

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MR. SNAPP: Object to the form.
BY MS. DICKINSON:
Q. Correct?
MR. SNAPP: And beyond the scope.
THE WITNESS: There was -- there were statements regarding that the delayed absorption was believed to reduce the abuse liability.
BY MS. DICKINSON:
Q. Okay. Statements in marketing, correct?
MR. SNAPP: Object to the form, beyond the scope.
THE WITNESS: The exact statements I'd have to see the materials. I'm not responsible for those materials.
BY MS. DICKINSON:
Q. I'm just asking you whether you know whether that message was delivered in marketing?
MR. SNAPP: Object to the form, beyond the scope.
THE WITNESS: Not that -- I'm not

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aware that that exact message.
MS. DICKINSON: Okay. We can take a look.
I'm going to hand this to you all together. Give me just a moment. I'm going to hand you a series of exhibits marked Exhibit 13, 14 and 15. Copies for your counsel are behind there.
(Documents marked for identification as Exhibit Purdue-Fanelli-13, 14 and 15.)
BY MS. DICKINSON:
Q. If you could put Exhibits 13, 14 and 15 in front of you, that would be great.
Okay. So for the record, Exhibit 13, 14 and 15 are a series of documents filed in the case in which the United States Department of Justice charged Purdue with criminal charges over the false marketing of OxyContin.
Are you familiar with that case?
A. Familiar with the case.
Q. Okay.
A. Well, yes.
Q. Are you familiar with the fact

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that Purdue was charged in that case, shown in 13, 14 and 15, with felony misbranding of its drug OxyContin?
MR. SNAPP: Object to the form, object as beyond the scope of the noticed deposition topics. He's not been designated to testify about the plea. He's not authorized on behalf of the company to speak on behalf of the company with respect to the plea.
BY MS. DICKINSON:
Q. Go ahead and answer.
A. Could you repeat the question, please.
Q. Are you familiar with the fact that Purdue was charged with felony misbranding of its drug OxyContin?
MR. SNAPP: Same objections.
BY MS. DICKINSON:
Q. In the year 2007?
A. I'm familiar that there was a case, but the details of what the charges were or what the plea was are not part of my responsibility or legal understanding.

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Q. Okay. You're familiar that there was a case, and do you understand that Purdue pled guilty to the charges in that case?
MR. SNAPP: Same objection, beyond the scope.
THE WITNESS: Yes.
BY MS. DICKINSON:
Q. Okay. All right. And let's take a look at -- for the record, let's just identify Exhibit 13 is a document called the Information in the federal criminal case that we were just talking about.
Do you see that title?
A. Yes.
Q. Okay. The document we marked as Exhibit 14 is Purdue's Plea Agreement.
Do you see that?
A. Yes.
Q. And the document we marked as Exhibit 15 is an Agreed Statement of Facts in that same case, correct?
A. Correct.
Q. I'd like you to take Exhibit 15, please, the Agreed Statement of Facts, and turn

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to paragraph 20.
Tell me when you're there.
A. I'm there.
Q. Okay. That paragraph reads, "Beginning on or about December 12th, 1995, and continuing until on or about June 30th, 2001, certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications, as follows."
Did I read that correctly?
A. Yes.
Q. Okay. And that is an agreed statement of fact that Purdue agreed to, correct?
MR. SNAPP: Object to the form, beyond the scope.
THE WITNESS: So, again, I'm not -- my responsibility is not with law and interpretation, so I'd have to -- I haven't seen this document prior.
BY MS. DICKINSON:

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Q. Okay. Can you turn to the last page.
A. Yeah.
Q. Or, actually, I'm sorry, could you turn to page 27 at the bottom.
A. Twenty-seven of the page ID?
Q. Yes.
A. Okay.
Q. And that page contains and it says for the defendant, Purdue Frederick Company, and it contains the signature of Robin Abrams, below it Michael Friedman, below it Howard Udell, correct?
A. Correct.
Q. And those -- Mr. Abrams, Mr. Friedman and Mr. Udell were all employed by Purdue Frederick Company at the time, correct?
A. It's Ms. Abrams, but, yes.
Q. So according to the paragraph we just read in the Information, that between 1995 and 2001, Purdue, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive and less subject to abuse and diversion, according to this document, the

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Agreed Statement of Facts, correct?
MR. SNAPP: Object to form, beyond the scope.
THE WITNESS: It says certain Purdue supervisors and employees, that's what it says, yes.
BY MS. DICKINSON:
Q. Okay. And the years 1995 to 2001, that was the first six years of the marketing of OxyContin; is that right?
MR. SNAPP: Object to the form.
THE WITNESS: Purdue was approved -- I think that's the date of approval. I'd have to look. I'm not sure when the marketing began. Usually they're not -- it's not marketed the day of approval. It takes some time.
BY MS. DICKINSON:
Q. Fair enough. Marketing would probably commence shortly after approval, correct?
A. Correct.
Q. Okay. And the years 1995 to 2001, Purdue was selling OxyContin, correct?

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A. Shortly after, yes, through 2001 until today.
Q. Let's just --
A. I don't know if we launched until January -- you said 2000.
Q. Let's do it this way: The years 1996 to 2001 --
A. Correct.
Q. -- Purdue was selling OxyContin during those years, correct?
A. Correct.
Q. In between those years, Purdue dispensed over a billion pills of OxyContin; is that right?
MR. SNAPP: Object to the form, also beyond the scope.
THE WITNESS: I have -- I don't have any knowledge of the number of pills.
BY MS. DICKINSON:
Q. Do you have any ballpark idea what they sold in the first five years?
A. No.
MR. SNAPP: Same objections.

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BY MS. DICKINSON:
Q. Okay. You can put that aside for a moment, but let's keep it handy.
A. All three or --
Q. Just keep all three, if you would.
A. Okay.
Document marked for identification as Exhibit Purdue-Fanelli-16.)
BY MS. DICKINSON:
Q. Dr. Fanelli, we're going to talk about some of the reports and studies that Purdue either was or wasn't aware of in the 1995 to 2001 time frame, okay?
A. Okay.
Q. I've handed you what has been marked as Exhibit 16.
This is an article that appeared in the New York Times dated May 29th, 2018.
Have you seen this article?
A. I believe I have.
Q. Okay. Let's turn to -- trying to find a page here -- oh, page 4, at the top there

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are pages.
A. Yes.
Q. If you turn to page 4. The second to last paragraph, if you would just quickly read that.
A. (Witness reviews document.) Okay.
Q. Okay. This article describes that in 1996, okay, so '96 just months after Purdue started selling OxyContin, that Purdue started learning that drug abusers were seeking out OxyContin and Purdue's other long-acting opioid MS Contin.
Was Purdue receiving those kind of reports in 1996?
MR. SNAPP: Object to the form and beyond the scope.
BY MS. DICKINSON:
Q. Go ahead.
A. What kind of reports? I'm sorry.
Q. The article talks about Purdue receiving reports that in 1996 that there were drug abusers seeking out OxyContin and MS Contin?

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MR. SNAPP: Object to the form and beyond the scope.
BY MS. DICKINSON:
Q. Was Purdue -- I'm asking is that accurate, was Purdue receiving those kinds of reports in 1996?
MR. SNAPP: Object to the form and beyond the scope.
THE WITNESS: I'm not aware of whether or not Purdue received -- we would have received adverse event reports, and that's part of our pharmacovigilance, but I'm not aware of what were received during that time period.
BY MS. DICKINSON:
Q. Okay. Who would know?
MR. SNAPP: Same objections, beyond the scope.
THE WITNESS: I'm not aware. I don't know who would have received those at the time.
BY MS. DICKINSON:
Q. Okay. Further down, the second

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to last paragraph on this page, page 4, it says, "In May 1996, five months after OxyContin's approval, Richard Sackler and Mr. Udell were sent an older medical journal article describing how drug abusers were extracting Morphine from MS Contin tablets in order to inject the drug, prosecutors reported. A Purdue" -- I'm sorry, we don't need to read the next sentence yet.
Was Purdue in 1996 sent medical journal articles describing how drug abusers were extracting Morphine from MS Contin tablets in order to inject the drug?
MR. SNAPP: Object to the form and beyond the scope.
THE WITNESS: I do not know.
BY MS. DICKINSON:
Q. We'd have to ask Mr. Sackler and Mr. Udell; is that right?
MR. SNAPP: Object to the form.
THE WITNESS: I'm not sure of the source or how to -- you know, how you would ask.
BY MS. DICKINSON:
Q. Well, this article says that

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Mr. Sackler and Mr. Udell were sent the journal article. So to verify whether that's true or not, I would have to ask those two individuals; is that right?
MR. SNAPP: Object to the form, beyond the scope.
THE WITNESS: It's a report from the prosecutors, not from those individuals so...
BY MS. DICKINSON:
Q. I'm not trying to be difficult.
I have not seen this document produced in this case, so I'm trying to figure out if this fact is accurate, and this reports that Mr. Sackler and Mr. Udell received a document. I'm trying to figure out who at Purdue could tell me if they actually received this document, and I assume Mr. Sackler is one of those people, correct?
MR. SNAPP: Object to form, object as beyond the scope.
THE WITNESS: I don't know if it came to others but if -- so what you said is correct.

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BY MS. DICKINSON:
Q. And if someone received this information in 1996, that was after OxyContin was on the market with the label that said delayed absorption is believed to reduce the abuse liability of the drug, correct?
MR. SNAPP: Object to the form. Object as beyond the scope.
THE WITNESS: What year? I'm sorry.
BY MS. DICKINSON:
Q. 1996, May of 1996.
A. So we looked at the label approved by FDA in '95, so that was in there.
Q. Okay. So --
A. Upon approval.
Q. Okay. So that -- this -- if this document exists, that would have been after the label -- after OxyContin went on the market with its label that said "delayed absorption is believed to reduce the abuse liability of the drug," right?
MR. SNAPP: Object to the form.
BY MS. DICKINSON:

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Q. That's after?
MR. SNAPP: Object to the form. Object as beyond the scope.
THE WITNESS: Yes, correct.
BY MS. DICKINSON:
Q. Do you know if Purdue or its executives told the FDA in 1996 about reports of abuse of its extended-release products?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: I don't know when conversations were held with FDA, at what time, actually.
BY MS. DICKINSON:
Q. You're not prepared to talk about that today?
MR. SNAPP: Object to the form.
THE WITNESS: Correct.
BY MS. DICKINSON:
Q. All right. Let's go to the next page, page 5. The very top paragraph says, "by the following year," and I assume that means 1997 because we were just talking about 1996.
A. Okay.

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Q. "Prosecutors wrote, that Purdue Pharma learned that drug addicts in Australia and New Zealand were abusing MS Contin and Dr. Goldenheim was sent an article from the American Family Physician, a publication, about the ease of extracting Morphine from MS Contin."
Do you know if in 1997 Purdue was receiving reports that drug addicts in Australia and New Zealand were abusing MS Contin?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: I do not know.
BY MS. DICKINSON:
Q. Okay. And do you know if Dr. Goldenheim was sent an article from the American Family Physician about the ease of extracting Morphine from MS Contin in 1997?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: I do not know.
BY MS. DICKINSON:
Q. And Dr. Goldenheim at that point in time, I believe we saw in the organizational charts we looked at this morning, was the head

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of medical affairs; is that right?
A. I'm not -- he was head of R&D. Whether those were combined at the time, I'm not sure.
Q. He was the head of --
A. Research and development.
Q. -- research and development, correct?
A. Correct.
Q. And then let's go to the next paragraph, "Then in 1998, as OxyContin's marketing campaign was taking off, Purdue Pharma learned of a medical journal study that appeared to undercut its central message - that OxyContin, as a long-acting opioid, had less appeal to drug abusers."
It goes on to say, "In the study, which was published in the Journal of Canadian Medical Association, researchers from the University of British Columbia in Vancouver interviewed local drug dealers and abusers to learn what legal drugs sold for on the black market. They found that MS Contin commanded the highest price of any prescription opioid with a

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30-milligram tablet that cost $1 at a pharmacy bringing up to $40 on the street."

Did I read that accurately?

A. Yes.

Q. Okay. Do you know in 1998 if Purdue Pharma was provided with that Canadian study that the article discusses?

MR. SNAPP: Objection, beyond the scope.

THE WITNESS: I do not know.

BY MS. DICKINSON:

Q. Do you know if Purdue Pharma was aware of that Canadian study that the article discusses?

MR. SNAPP: Objection, beyond the scope.

THE WITNESS: No, I don't know.

BY MS. DICKINSON:

Q. All right. The article goes on to say, "In an accompanying editorial, a Canadian physician, Dr. Brian Goldman, wrote that the findings turned thinking about the supposed safety of long-acting opioids like OxyContin on its head by showing that drug

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abusers 'coveted' such drugs. 'This should ring alarm bells,' Dr. Goldman, who was then a paid speaker for Purdue Pharma, wrote in the editorial."

Do you know if in 1998 Purdue Pharma received a copy of that editorial?

MR. SNAPP: Objection, beyond the scope.

THE WITNESS: I do not know if we did.

BY MS. DICKINSON:

Q. Do you know if Purdue Pharma ever provided a copy of either the Canadian study or the editorial to the FDA?

MR. SNAPP: Objection, beyond the scope.

THE WITNESS: I do not know. We would -- I would have to look at our pharmacovigilance reports. Following approval of any drug, we send to FDA for the first three years a collection of adverse events that occur and then at least annually thereafter, so those kinds of reports would be included in

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those reports to the FDA, but I'm not aware of this particular.

BY MS. DICKINSON:

Q. So this is the kind of thing that would be included in an adverse event pharmacovigilance follow-up after approval; is that correct?

A. Potentially. It depends on the characteristics of the report.

Q. Okay. And where would I look to see if that was submitted to the FDA?

MR. SNAPP: Objection, beyond the scope.

THE WITNESS: It would be in the adverse -- we call them PSURs, periodic safety update reports, they've changed in what they've been termed over time, the reports submitted to FDA.

BY MS. DICKINSON:

Q. Do you know -- this article says that Purdue did not send the Canadian study to the FDA or tell its sales representatives about that.

Do you know if that's accurate?

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MR. SNAPP: Objection, beyond the scope.

THE WITNESS: I do not know if that's accurate or not.

BY MS. DICKINSON:

Q. Okay. Do you know if Purdue took the position it was not required to send the FDA the Canadian study or the editorial?

MR. SNAPP: Objection, beyond the scope.

THE WITNESS: I do not know what was said.

BY MS. DICKINSON:

Q. Do you know at this point in time in 1998 whether Purdue was going to the FDA and say -- and telling the FDA that they thought the label that delayed absorption is believed to reduce abuse liability of a drug should be changed?

MR. SNAPP: Objection, beyond the scope.

THE WITNESS: I'm not aware of the -- you know, the label was changed around 2001, and there were discussions,

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but I'm not aware of where the exact dates of those discussions began.

BY MS. DICKINSON:

Q. So the label took that statement out, the delayed absorption is believed to reduce the abuse liability of the drug in 2001; is that right?

A. I believe that was the date. I'd have to check the exact date.

Q. Do you know if in 1996 or '97 or '98, Purdue was telling the FDA that label -- that part of the label should be changed?

MR. SNAPP: Objection, beyond the scope.

THE WITNESS: I'm not aware that Purdue was doing that.

BY MS. DICKINSON:

Q. But what we do know is that at least between December 12th, 1995 and continuing until about June 30th, 2001, certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion and less likely to cause

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tolerance and withdrawal than other pain medications. That's what we looked at in the previous document, correct?

MR. SNAPP: Object to the form and objection beyond the scope.

THE WITNESS: That is what's stated in that document, yes.

BY MS. DICKINSON:

Q. That document that was signed by officials at Purdue, correct?

MR. SNAPP: Same objections.

THE WITNESS: Yes.

BY MS. DICKINSON:

Q. All right. Let's move on to talk about the study submitted to the FDA.

MR. SNAPP: Are you done with Exhibits 13, 14 and 15?

MS. DICKINSON: Let's just keep them. I think so, but if you don't mind keeping those three somewhere in the vicinity. I think we're done with the other stuff that we've looked at here.

(Document marked for identification as Exhibit

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Purdue-Fanelli-17.)

MS. DICKINSON: I'll hand you this monster copy of something we're going to look at one page of, but I'm sorry, it was the complete document, and I certainly don't want to start pulling stuff out of documents that were produced to us, so here it comes. I'm really sorry, this is going to be a little heavy.

BY MS. DICKINSON:

Q. Okay. I'm going to hand you what has been marked as Exhibit 17.

And this is a document produced to us by Purdue in this litigation that at the start of the document bears the Bates number PURCHI000667209.

Do you see that?

A. Yes.

Q. Okay.

A. Sorry.

Q. And what I believe this is is a portion of documents that were submitted to the FDA regarding OxyContin.

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Is that a fair way to characterize what this appears to be in this document?

A. I believe this comes from the Freedom of Information office at FDA.

Q. Okay.

A. I believe what this is -- I have to see the -- maybe the request was in here. Oh, here it is. No, that's not it.

I believe -- and on page 3 it says NDA 20553, which is the NDA for the original OxyContin. I believe this is the Freedom of Information information that's provided upon approval of an NDA.

Q. Fair enough.

A. Yeah.

Q. And I think it matters little for the purpose of this discussion --

A. Okay.

Q. -- but I just want to make sure we're clear that the best place or the smallest place I can find what I'm going to be talking about with you --

A. Okay.

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Q. -- was in this document.
So this appears to be a Freedom of Information Act request that was responded to by producing parts of the NDA for the original OxyContin; is that right?
A. Yes.
Q. Okay.
A. Yes.
Q. Can we take a look at page PURCHI000667249. So 7249 are the last four numbers.
A. Okay, I'm there.
Q. Okay. I'm not. Sorry, just give me a second. Okay. I'm sure my exhibit has the right page.
Okay. Who at Purdue decided which studies would be submitted to FDA for the original OxyContin?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: There were discussions between FDA and Purdue about the development and -- development program, including the studies, and what

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would be part of the NDA. Today we have, now the PDUFA is here, pre-NDA meetings. Back then it was much less formal, but there were discussions back and forth with FDA that I'm -- even before I joined that I'm aware of on what was required for the approval.
BY MS. DICKINSON:
Q. Okay. Do you know who was involved in that process at -- from the Purdue side?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: Which process, the discussions with FDA?
BY MS. DICKINSON:
Q. Who was involved in deciding what studies would be submitted to the FDA at Purdue, not from the FDA side?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: So that would have been -- we talked about in R&D, but regulatory affairs function is to --

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we'll talk about that, but -- I mean, we could talk about that -- is to interpret FDA regulations, what the requirements for submissions and so forth. So regulatory affairs would be involved and so would all the individuals responsible for conducting those trials in R&D mostly, but it could have been other folks as well.
BY MS. DICKINSON:
Q. Do you know who specifically at Purdue was involved in the process of deciding which studies would get submitted to the FDA with respect to the original OxyContin?
MR. SNAPP: Object to the form, objection as beyond the scope.
THE WITNESS: It would have been the individuals that we talked about in that time period in regulatory affairs and R&D who were on that project.
BY MS. DICKINSON:
Q. And do you know who that is? We can look.
MR. SNAPP: Objection, beyond the

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scope.
THE WITNESS: Do you want to look at the org chart?
BY MS. DICKINSON:
Q. If you can -- well -- so at that time period back in 1996, I assume we'd be talking about the 1995 org chart that we marked earlier as Exhibit 8; is that correct?
A. Yes.
Q. Okay.
A. Well, I'm not sure if there were changes, what time period, but that would be a good place to look.
Q. Okay. And we said that the scientific and medical affairs group started at the page that starts 601 headed by Paul Goldenheim.
I'm just trying to figure out for the studies that we see on the document we were just looking at that were submitted to the FDA, who on this org chart was responsible for deciding what got submitted to the FDA?
MR. SNAPP: Objection, beyond the scope.

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THE WITNESS: So for -- I'm not aware of that, but I can tell you the positions that would have been responsible. There's a project manager and there are several individuals. I'm not sure who was the project manager at the time. So under Paul Goldenheim, there are project managers and then within each product, you talked about MS Contin, OxyContin, there's a team that would be the ones determining what studies go into an NDA application, including the regulatory -- the main functions involved in that would be the clinical representative, the R&D, you know, the regulatory and then the team in general.

BY MS. DICKINSON:

Q. Okay. Just so I understand, you don't know specifically for OxyContin who those people were that decided on the studies, but, typically, for a drug like OxyContin, there would be a team of people, one person would -- and they would be in this case under Paul

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Goldenheim, right?

MR. SNAPP: Object to the form.

THE WITNESS: As the head of the R&D group at the time, yes.

BY MS. DICKINSON:

Q. Okay. And that would include positions like the project manager that was assigned to OxyContin; is that right?

A. Yes.

Q. And a -- I think you said clinical representative?

A. Clinical or medical, you know, depends on, you know, what their -- clinical scientists.

Q. Okay. And someone else from R&D; is that correct?

A. Regulatory would be involved in providing guidance on what, you know, FDA's guidances or requirements were for a particular agent.

Q. How do I find out who the people were that participated in deciding what studies were submitted to the FDA?

MR. SNAPP: Objection, beyond the

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scope.

THE WITNESS: There -- and what time frame are we talking about?

BY MS. DICKINSON:

Q. This is OxyContin, so 1995ish.

A. If there were formal conversations between the company and FDA, they would be in records in the regulatory department, we call them contact reports, and that might provide those -- that information.

Q. Is there someone that signs off on the studies that are submitted to the FDA at the end of the day?

A. Yes, on the individual studies someone signs, yes.

Q. Who is that?

A. Usually it's the clinical leader, the one that I mentioned on the particular product, the statistician who was part of that project, and those are the prime individuals who would sign off on the document.

Regulatory is on there, depends on the document at the time.

Q. Who signs --

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A. That's the authors.

Q. Sorry. Are you finished with your answer?

A. Sorry.

Q. Who signs off on the NDA submission?

A. The actual sign person on the cover letter and the form, the FDA form is the regulatory representative.

Q. Okay.

A. And those forms, for an NDA it's a 365H FDA form, and that's just an -- it's the person -- mainly the contact person on that, but that's where the sign-off for the entire NDA occurs.

Q. Okay. And is there anyone else that would have had to sign off on the table of studies that was listed in the NDA for OxyContin?

MR. SNAPP: Object to the form, objection as beyond the scope.

THE WITNESS: I'm not aware of at that time what the procedure was, but those decisions are made at the

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recommendation and decisions are made at a project team level but approved by or -- approved by the head of R&D. In other words --

BY MS. DICKINSON:

Q. So at that time, that was Paul Goldenheim?

A. Correct.

Q. All right. Let's talk for a minute about the table of studies.

And that, again, for the record, is contained within Exhibit 17, the last page or last few numbers ending in 249.

On that page it summarizes or Purdue summarizes the totality of the controlled clinical trials that were submitted to FDA when Purdue was asking FDA to approve OxyContin as safe and effective for the treatment of chronic pain, correct?

MR. SNAPP: Object to the form. Objection as beyond the scope.

Can you give the witness a chance to look at the document also?

MS. DICKINSON: Of course.

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THE WITNESS: And, actually, I think you said Purdue -- this is the report of the medical officer at FDA, so this is -- what we're looking at is when an NDA is approved, FDA writes up -- they used to be called the summary basis of approval. Now it's just a review on the website, but, anyway, that's what this is so this --

BY MS. DICKINSON:

Q. Fair point, actually. Can I clean it up?

A. Yeah.

Q. This is a part of what we call the medical officer review, right?

A. Correct.

Q. It's commonly referred to as the MOR, right?

A. Correct.

Q. Okay. And so this piece is a summary by the medical officer review, whoever did that, I think it was Curtis Wright in this case --

A. That's correct.

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Q. -- of the clinical studies that were submitted to the FDA by Purdue when OxyContin was being approved, correct?

A. Correct.

Q. Okay. And under "Clinical Studies" we see a section called "Controlled Trials."

Do you see that?

A. Yes.

Q. And underneath that are listed six studies -- or six controlled trials, correct?

A. Yes.

Q. Okay. Would you agree with me that randomized, double-blind, controlled studies are generally considered to be the gold standard of clinical studies that can be performed?

MR. SNAPP: Object to form. Objection as beyond the scope.

THE WITNESS: Repeat -- so the science says for approval of drugs has changed over time, especially in this area, understanding, you know, what

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trials need to be provided to demonstrate safety and efficacy have evolved over time, and it depends on when we're talking about what is considered appropriate at those various times.

BY MS. DICKINSON:

Q. I'm trying to ask a little bit more basic question.

There are different types of trials and studies, correct?

A. That's correct.

Q. What I've been told, and I just want to see if I'm accurate, is that randomized, double-blind, controlled studies, that type of study -- that's a type, correct?

A. Yes.

Q. And those are typically considered to be the gold standards of clinical trials, correct?

MR. SNAPP: Object to the form. Objection beyond the scope.

THE WITNESS: Yes, those are trials if -- you know, again, as I say,

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the requirements -- for instance, you can't do a double-blind study in oncology, you know, because you're not going to give someone who doesn't have cancer a chemotherapeutic, for instance.

So it really depends what the gold standard for a particular time and indication varies.

BY MS. DICKINSON:

Q. Okay. Let's just talk about this indication.

A. Sure.

Q. Chronic pain.

At that time and for that indication, randomized, controlled clinical trials, those would have been the gold standard at that time, correct?

MR. SNAPP: Object to the form. Objection as beyond the scope.

THE WITNESS: There were discussions with FDA about what -- how to do these kinds of trials and what the appropriate patients -- whether -- you notice there are some cancer trials

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here, what the appropriate design of those would be.

So I wouldn't say that a particular design was the gold standard.

BY MS. DICKINSON:

Q. Okay.

A. It's a collection of studies.

Q. So you don't believe that random, controlled clinical trials are sort of at the top or the most reliable set of studies; you don't believe that?

MR. SNAPP: Object to the form.

THE WITNESS: No. I -- they are important clinical trials, and if they're possible and necessary, they provide evidence, strong evidence.

BY MS. DICKINSON:

Q. Okay. And to get approval for a drug, a company has to submit adequate and well-controlled studies to support its application, correct?

A. That's correct.

MR. SNAPP: Object to the form. Objection as beyond the scope.

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BY MS. DICKINSON:

Q. That means submitting clinical -- controlled clinical trials, correct?

MR. SNAPP: Same objections.

THE WITNESS: Yes.

BY MS. DICKINSON:

Q. Okay. And Purdue submitted six clinical trials for OxyContin, correct?

MR. SNAPP: Objection, beyond the scope.

THE WITNESS: So this whole -- controlled clinical trials is what you're saying because this whole table is all the -- there are many pharmacokinetic studies. The whole list, there's more than six.

BY MS. DICKINSON:

Q. Fair. Can I ask a different question?

A. Yes.

Q. That is a fair point.

Purdue submitted six controlled trials in support of its application for approval for OxyContin, correct?

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MR. SNAPP: Objection, beyond the scope.

THE WITNESS: That's correct.

MR. SNAPP: Okay. We've been going a little more than an hour.

MS. DICKINSON: I think we'll take a break when we're finished with this document, if that's okay, and then we can talk about eating.

THE WITNESS: Sounds good.

MS. DICKINSON: Not trying to starve you.

BY MS. DICKINSON:

Q. Okay. So I just want to make sure when I look at these documents that I have an understanding.

This would be the totality of the controlled trials that Purdue submitted in support of the safety and efficacy of OxyContin for long-term use; is that right?

MR. SNAPP: Objection, beyond the scope.

THE WITNESS: I believe that's true. To know for certain, I would look

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at Purdue's table of contents. This is, again, the medical reviewer. I haven't studied this to know whether Dr. Wright left one out.
BY MS. DICKINSON:
Q. Okay.
A. But I believe this is the list.
Q. Fair enough. Unless Dr. Wright made a mistake --
A. Correct.
Q. -- this is the list of the controlled trials in support of safety and efficacy of OxyContin for long-term use that Purdue submitted to the FDA; correct?
MR. SNAPP: Object to the form. Objection as beyond the scope.
THE WITNESS: Correct.
BY MS. DICKINSON:
Q. Okay. This is the list of the controlled trials in support of the safety and efficacy of OxyContin to treat chronic pain as well, correct?
MR. SNAPP: Same objections.
THE WITNESS: The controlled

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trials, yes.
BY MS. DICKINSON:
Q. Okay. And chronic pain is commonly defined as lasting for longer than three months; is that right?
MR. SNAPP: Objection as beyond the scope.
THE WITNESS: It depends on what definition you're -- you know, we're talking about. Definition in terms of diagnostic criterion in a physician's office or regulatory -- you know, they're different.
FDA's definition has also evolved over time. At one -- the indication for these products at one time just said weeks, you know, and then it's weeks, months or longer, and now it's long term. So the regulatory standard has changed for these trials.
BY MS. DICKINSON:
Q. Back in 1996 was the accepted definition of chronic pain pain that lasted longer than 90 days?

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MR. SNAPP: Object to the form. Objection as beyond the scope.
THE WITNESS: I'm not aware of in that year what the definition of chronic pain was.
BY MS. DICKINSON:
Q. Okay. Let's look quickly at the controlled trials. There is a column that talks about the duration of those controlled trials.
Do you see that?
A. Yes.
Q. And the first controlled trial that's listed, it was studied on patients that took OxyContin for five days; is that correct?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: It says five days plus or minus, I'm not sure what the plus or minus indicates. I could look at the --
BY MS. DICKINSON:
Q. Okay. And the duration for the second clinical trial or controlled trial was also listed at five days, and I see plus or

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minus, correct?
A. That's correct.
Q. All right. The third was seven-day clinical -- or controlled trial.
Do you see that?
A. Correct.
Q. The fourth was a 14-day controlled trial, correct?
A. That's correct.
Q. The fifth was a seven-day controlled trial?
A. It says -- yes, seven days. I'm not sure what XO stands for.
Q. Okay. And the last, sixth controlled trial was a study on patients who just took a single dose; is that right?
MR. SNAPP: Object to the form.
THE WITNESS: That's correct.
BY MS. DICKINSON:
Q. Okay. So the longest duration of the controlled studies that Purdue submitted to the FDA in support of safety and efficacy of OxyContin for treatment of chronic pain was 14 days, correct?

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MR. SNAPP: Object to the form. Objection as beyond the scope.
THE WITNESS: In the initial clinical -- the controlled trials the longest is 14 days, correct.
BY MS. DICKINSON:
Q. Okay. So none of the controlled studies submitted to the FDA showed safety or efficacy beyond 14 days, correct?
MR. SNAPP: Object to the form. Objection as beyond the scope.
THE WITNESS: That's correct.
MS. DICKINSON: I think this is a good time to take a break.
THE VIDEOGRAPHER: Standby, please. Remove your microphones. The time is 11:29 a.m. Going off the record.
(Brief recess.)
THE VIDEOGRAPHER: All right. We are back on the record. The time is 11:42 a.m.
BY MS. DICKINSON:
Q. Dr. Fanelli, we're back on the

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record.
A. Yes.
Q. We talked before going off camera about the clinical studies and the controlled studies that were done and submitted regarding OxyContin. We're going to stay on the subject of OxyContin, but let's talk about the studies that were not done at the time of OxyContin approval.
At the time of approval of OxyContin in 1995, Purdue had not conducted clinical studies on how addictive or prone to abuse OxyContin might be; is that right?
MR. SNAPP: Object to the form. Objection as beyond the scope.
THE WITNESS: That's correct.
BY MS. DICKINSON:
Q. Okay. I'm going to hand you what has been marked as Exhibit 18, and it's coming around.
(Document marked for identification as Exhibit Purdue-Fanelli-18.)
BY MS. DICKINSON:

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Q. And, for the record, Exhibit 18 is an e-mail chain. It starts with Bates number PKY181376452. That e-mail chain is dated June 16th, 1999. At the top it is from David Gordon to Dr. Robert Kaiko.
And a little bit further down the page, there was an earlier e-mail in the chain from Dr. Kaiko to a number of individuals, Dr. Lloyd Haskell, David Gordon, Teresa Baker and Marco Ermini, I think. It copies Mike Innaurato, Ellen?
A. Ingber.
Q. I'm really do not do well with her name, Ingber.
A. It's Ellen Ingber.
Q. And Andrew Albright.
Do you see that?
A. Yes.
Q. Okay. And that part of the e-mail chain is -- from Dr. Kaiko is dated June 15th, 1999, correct?
A. Yes.
Q. Who is Dr. Kaiko?
A. We mentioned him previously as

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the head of one of the R&D departments or one of the Purdue departments, I can't remember what it was at that time.
Q. Was he the chief scientist in R&D back in 1999?
A. I believe that's correct.
Q. And if you would, just take a minute to review Dr. Kaiko's portion of the e-mail chain. I don't think you need to read every word, but I'll tell you what my question is going to be.
In this e-mail chain, is Dr. Kaiko proposing a study program for OxyContin is going to be my question, so take a minute to review the e-mail.
A. (Witness reviews document.)
I've looked at it quickly.
Q. My question is in the e-mail generally is Dr. Kaiko proposing a study program for OxyContin?
A. Yes, it appears so.
Q. Okay. Then that's on page 2 there's a section called "Proposed Study Program," correct?

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A. Correct.
Q. Okay. And on page 2 at the top, Dr. Kaiko identifies the reasons that would support further investment in OxyContin, including the following, and he says, OxyContin has better patent protection than any of the other analgesics and any such investment in the growth of OxyContin is also relatively protected.
His second reason is that OxyContin has a reasonable number of differentiating properties from other analgesics, but these differentiating properties have not been sufficiently studied or exploited.
Three, the acceptance of this strong analgesic in non-cancer pain is also quite unique and begs for further development in that very large market.
Do you see that?
A. Yes.
Q. Did I read that correctly?
A. Yes.
Q. And Dr. Kaiko here is identifying those three reasons as the business reasons for

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wanting to run additional studies, correct?
MR. SNAPP: Object to the form.
THE WITNESS: It says these are the reasons to support investment, yes.
BY MS. DICKINSON:
Q. Okay. And that investment would be an investment through conducting the proposed study program that he proposes, correct?
MR. SNAPP: Object to the form.
THE WITNESS: It includes budget, right.
BY MS. DICKINSON:
Q. I'm sorry. I think we were probably talking over each other. What was your answer?
A. I'm sorry. That's correct.
Q. Okay. None of those three reasons that Mr. Kaiko at least is identifying here for wanting to run this proposed study program has to do with safety, correct?
MR. SNAPP: Object to the form.
THE WITNESS: It's not clear whether or not they're safety.
BY MS. DICKINSON:

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Q. The three reasons he offers in this first paragraph, none of those have to do with safety, correct?
MR. SNAPP: Object to the form.
THE WITNESS: Differentiating properties could refer to safety.
BY MS. DICKINSON:
Q. Okay. Other than the differentiating properties which you think might refer to safety, do you see anything else about safety in the reasons that Dr. Kaiko is offering for the support of further investment in OxyContin?
MR. SNAPP: Object to the form.
THE WITNESS: So this is -- it doesn't specifically state that, but a strong analgesic in non-cancer pain may have some safety issues related to it.
BY MS. DICKINSON:
Q. Okay. Let's go down to under the proposed study program. There's a section called "Therapeutic Trials."
Do you see that?
A. On the same -- yes.

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Q. And number one on Dr. Kaiko's list is -- and one of the proposed study program therapeutic trials he is proposing to run is on iatrogenic addiction in non-cancer pain patients.
Do you see that?
A. Yes.
Q. And he proposes to conduct that study in the year 2000 or 2001, correct?
A. Yes, that's what it says.
Q. And we talked about -- well, we didn't talk about it earlier, but Purdue did not take his recommendation and conduct that study in the year 2000 or 2001, correct?
MR. SNAPP: Object to the form. Objection as beyond the scope.
THE WITNESS: I'm not aware, you know, whether Purdue did or not.
BY MS. DICKINSON:
Q. Are you aware at any time between 1995 and 2017 whether Purdue conducted any clinical studies on iatrogenic addiction with respect to OxyContin?
MR. SNAPP: Objection, beyond the

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scope.
THE WITNESS: So Purdue is conducting postmarketing required studies of currently -- what are the years that you asked?
BY MS. DICKINSON:
Q. I asked you from 1995 to 2017.
A. So we have postmarketing required studies both for OxyContin and for the class to study misuse, abuse, addiction, overdose and death as required by those postmarketing studies. So those studies have been going on, I can't remember the year they started, at least five years, to study.
Q. Okay. And those were the studies that were required by the FDA, correct?
A. It was part of a postmarketing requirement, yes.
Q. Okay. So I just want to clear up the history.
The FDA at some point in time, you think it was about five years ago, required Purdue to conduct postmarketing studies on addiction and abuse with respect to OxyContin;

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is that correct?
A. I don't remember the exact year starting, but, yes, it's part of a postmarketing commitment.
Q. Okay. Up until the time that the FDA required those studies, had Purdue conducted any studies on addiction or abuse with respect to OxyContin?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: We had -- in the reformulated OxyContin has abuse deterrent properties, so we have clinical trials looking at the effect of that reformulation.
BY MS. DICKINSON:
Q. I'm just talking about the original formulation.
A. Okay.
Q. If I could.
A. Yes.
Q. The original formulation, to your knowledge prior to the FDA requiring these addiction and abuse studies, whenever that was,

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the last five years sometime, had Purdue ever conducted any studies on the original formulation regarding iatrogenic addiction?
MR. SNAPP: Object to the form, objection as beyond the scope.
THE WITNESS: Not that I'm aware of.
BY MS. DICKINSON:
Q. So Purdue from the time of this e-mail in 1999 to roughly five years ago, when it was required to do so by the FDA, did not take Dr. Kaiko's recommendation and conduct studies on iatrogenic addiction with respect to the original formulation of OxyContin, correct?
MR. SNAPP: Object to the form. Objection as beyond the scope.
THE WITNESS: Could you repeat the question. I'm sorry.
BY MS. DICKINSON:
Q. Yes. I'm just confirming what I think you told me a minute ago.
So Purdue from 1999, when Dr. Kaiko was recommending doing a study on iatrogenic addiction in non-cancer patients,

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from that time in 1999 up until the FDA required it to several years ago, Purdue did not take Dr. Kaiko's recommendation and conduct this study that he was proposing, correct?
MR. SNAPP: Same objections.
THE WITNESS: Again, I'm not aware, so I assume, you know, the design and science around those studies is an evolving science, but, as far as I know, no, those studies were not conducted.
BY MS. DICKINSON:
Q. Okay. Let's go to the page that talks about this proposed iatrogenic addiction study, which at the bottom is PKY181376455, so it's a couple pages beyond that.
A. I got it.
Q. Do you see it?
A. Yes.
Q. Okay. And Dr. Kaiko here in the iatrogenic addiction section, he talks about the rationale for conducting such a study.
He says, "The around-the-clock use of opioids in the management of chronic non-cancer pain remains controversial; there is

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certainly not a consensus within the medical or regulatory communities in most territories. Long-term, well-controlled studies demonstrating either no or an insignificant incidence of iatrogenic addiction and drug diversion would encourage earlier and more prolonged use of OxyContin in chronic non-cancer patients in whom non-opioids are not sufficiently safe and/or effective."

Did I read that correctly?

A. Yes.

Q. Okay. And the study that Dr. Kaiko was proposing was a means of resolving that lack of consensus; was it not?

MR. SNAPP: Object to the form. Objection as beyond the scope.

THE WITNESS: The design was to investigate that rationale. I don't know about resolving a consensus.

BY MS. DICKINSON:

Q. Okay. And the study was --

A. Providing evidence.

Q. The study was needed because Purdue had not conducted prior studies on that

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subject, correct?

MR. SNAPP: Objection, beyond the scope.

THE WITNESS: There were no data regarding that on that particular topic.

BY MS. DICKINSON:

Q. Okay. And until the study that Purdue is currently working on, Purdue has no data on that particular topic as well, correct?

MR. SNAPP: Object to the form. Objection as beyond the scope.

THE WITNESS: There is no -- what we talked about was a clinical trial design. There is information related to abuse and addiction, but there's no clinical trial.

BY MS. DICKINSON:

Q. Fair.

A. As is stated, yes.

Q. And that was true when Purdue was marketing OxyContin as believed to reduce the abuse potential of the drug, the extended-release formulation, correct?

MR. SNAPP: Object to the form.

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Objection as beyond the scope.

THE WITNESS: So what was true, that there was no clinical?

BY MS. DICKINSON:

Q. That there was no clinical trial, correct?

A. Correct.

MR. SNAPP: Same objections.

BY MS. DICKINSON:

Q. Let's look back at -- you may have to dig for this for a minute -- Exhibit 15, the Agreed Statement of Facts in the criminal case against Purdue by the United States Department of Justice. That's Exhibit 15.

A. Mm-hmm.

Q. Can we take a look at paragraph 14. Let's start with the first capitalized Purdue.

"Purdue did not have, and did not provide the FDA with, any clinical studies demonstrating that OxyContin was less addictive, less subject to abuse and diversion, or less likely to cause tolerance and withdrawal than other pain medications."

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Do you see that in the Agreed Statement of Facts that Purdue signed in 2007?

A. Just want to confirm which document we're looking at.

Fourteen, is that --

Q. Yes.

A. Yeah. (Witness reviews document.)

Yes, I see that.

Q. Okay. And do you believe that to be true, that Purdue did not have and did not provide the FDA with any such clinical studies?

MR. SNAPP: For completeness, can you read the first part of that sentence as well.

MS. DICKINSON: Sure.

BY MS. DICKINSON:

Q. Let's -- I'll back it up in just a second.

But do you believe that that statement is accurate "and Purdue did not have, and did not provide the FDA with, any clinical studies demonstrating that OxyContin was less addictive, less subject to abuse and diversion,

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or less likely to cause tolerance and withdrawal than other pain medications"?
MR. SNAPP: Object to the form. Objection as beyond the scope.
THE WITNESS: What this talks about is clinical studies only, and that's what it says, yeah.
BY MS. DICKINSON:
Q. And that was true, there were no such clinical studies; we just talked about that a minute ago, correct?
MR. SNAPP: Same objections.
THE WITNESS: Correct.
BY MS. DICKINSON:
Q. Okay. But even though there were no such clinical studies, let's turn to paragraph 20 again.
A. The same document?
Q. Yep.
"Beginning on or about December 12th, 1995, and continuing until on or about June 30th, 2001, certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted

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OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications."
That fact was a fact that Purdue signed off on in its Agreed Statement of Facts in its criminal case, correct?
MR. SNAPP: Object to the form. Objection as beyond the scope.
THE WITNESS: That is correct.
BY MS. DICKINSON:
Q. All right. Put that aside for a moment.
A. Excuse me, this e-mail too?
Q. You can put aside that e-mail as well.
A. Okay, thanks.
(Document marked for identification as Exhibit Purdue-Fanelli-19.)
BY MS. DICKINSON:
Q. All right. So I'm going to hand you what's been marked as Exhibit 19. And Exhibit 19 is a spreadsheet that was produced to

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plaintiffs by Purdue in this case. It bears the Bates number at the bottom PPLCC016000115515 as the starting Bates number; is that correct?
A. Yes.
Q. Did I read that number correctly?
A. Yes.
Q. This appears to be a spreadsheet containing the clinical trials for OxyContin, correct? If you want to take a minute to look through it.
A. I have it.
Q. Actually, I'm not sure I said that right. It appears to be a spreadsheet that lists studies that were done with respect to OxyContin, correct, not just clinical trials?
A. Let me look through.
(Witness reviews document.)
Yes, that's what it appears to be.
Q. Okay. And it lists a number of studies, correct?
A. Yes.
Q. Okay. More than the six clinical trials that were submitted to the FDA,

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obviously, right?
MR. SNAPP: Object to the form.
THE WITNESS: There's many. I'm not -- yes.
BY MS. DICKINSON:
Q. Okay. And it has a column on I guess kind of in the -- or actually towards the right-hand side that notes whether each study was published, correct?
A. Looking at "Report"? Is that the column, it says Report (CSR --
Q. I'm sorry. There's one that says "Publication" right next to --
A. Oh, yes.
Q. -- the left of "Report."
A. Yeah.
Q. Do you see that?
So it has a column noting if each study was published; is that right?
A. I would have to assume. I haven't seen this before, and there aren't a lot of descriptions of what those -- I don't know if it means in a scientific publication or just produced as a final document.

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Q. Okay. And I guess whatever it means, there are nos in the publication column for some of these studies, correct?
A. Yes.
Q. And the "Report" column has "CSR and/or literature" in parentheses. What does CSR and/or literature mean to you?
A. CSR is a clinical study report, and literature -- and I see like the first one lists Journal of Clinical Psychopharmacology, whether or not it was in a literature journal.
Q. Okay. So that column appears to tell which studies regarding OxyContin were either -- either did not have a clinical study report written up or if they were published, where it was published, correct?
MR. SNAPP: Object to the form.
THE WITNESS: That's what that column says. I'm not aware -- you know, I can't tell from this if all these studies were conducted or they were just protocols, plan, so I'm not -- it doesn't have enough context.
BY MS. DICKINSON:

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Q. Who would I ask to find out whether any of these studies were conducted, finished, that sort of thing, who would I ask?
A. Whoever produced this table, but it doesn't have an author.
Q. All I have is Purdue Pharma as the author, so I'm asking you, do you have any idea who at the company for OxyContin might know which studies were not finished or not completed, which studies were published, facts of that nature?
A. The clinical -- the clinical research, when we looked at the org chart, the clinical research individuals would be -- are responsible for these trials, and I'm -- I haven't read every line, but I'm assuming these are all clinical trials. But the clinical research group or medical research, those individuals.
Q. Okay. This appears to list studies between 1988 and 2005. In that time frame for OxyContin, who might be the person that might have the most knowledge about whether studies were completed, why they weren't

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completed and facts of that nature?
MR. SNAPP: Object to the form. Objection as beyond the scope.
THE WITNESS: The clinical research group.
BY MS. DICKINSON:
Q. And there are a number of studies on this table that have the notation under publication of no, correct?
MR. SNAPP: Object to the form.
THE WITNESS: There's -- I see no CSR.
BY MS. DICKINSON:
Q. Under publication, though, where it says yeses and nos, there are a number of notations where it reflects --
A. Oh, I see, sorry. I was on the wrong column.
Q. -- no in the publication column. Is that accurate?
MR. SNAPP: Same objection.
THE WITNESS: I see no with an asterisk, and I see no as well, that is correct.

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BY MS. DICKINSON:
Q. Okay. And under the report column, the only journal notation I see in the report column is that very first study that's listed in this table; is that accurate?
A. Yes.
Q. Okay. Put those aside.
(Document marked for identification as Exhibit Purdue-Fanelli-20.)
BY MS. DICKINSON:
Q. I'm going to hand you what I have marked as Exhibit 20, coming around.
Okay. And Exhibit 20 is another document that was produced to us by Purdue in this matter bearing the Bates number at the bottom PPLPC013000138890.
Do you see that?
A. Yes.
Q. Okay. And the title on this document is "OxyContin Clinical Studies."
Do you see that?
A. Yes.
Q. Okay. This document appears to

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list studies ranging from 1988 to 2005; is that accurate?
A. Yes.
Q. Okay. And this document also indicates for each study whether the study was completed and if it was published in a journal where it was published.
Do you see that?
A. Yes.
Q. And there are a number of studies that I believe are all highlighted in gray, but at least the first few are, where it notes that the study was completed but no CSR was written.
Do you see that?
A. Yes.
Q. And a CSR is the clinical study report, correct?
A. Correct.
Q. So those notations would mean that studies were completed but no report was actually written up on the study; is that right?
MR. SNAPP: Object to the form.
THE WITNESS: The subheading of the beginning of this says "Listed in

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IND Annual Reports," so I assume these were pulled out, that's where the source for these. So in the annual report, it must -- it stated that, that at that time in that annual report. I can't -- I don't know if a CSR subsequent or outside of the annual report appears somewhere else.
BY MS. DICKINSON:
Q. Okay. What is the IND annual report?
A. So once investigation of new drug application is submitted, every year you have to update the FDA on the safety -- mostly around safety, but conduct of studies is also a part of that requirement, so those would be listed in there, what studies were conducted.
Q. And who is in charge of the IND annual reports at Purdue in this time frame? Let's even just say 1995 to 2005.
A. So regulatory affairs would submit it. The individuals, each of the disciplines responsible for the different sections, so pharmacovigilance would give a

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report of adverse events that were reported during that year. There's a time period, of course, 12-month time period. Medical affairs or clinical, clinical research, the same folks we were talking about, would report on ongoing clinical trials. There's a section of the IND annual report that talks about ongoing clinical trials, where you list any adverse event -- you know, the listing, discontinuations and so forth that are part of that annual report.
Q. Okay. And this document notes that there are several studies, we'll just take the examples on the first page, that -- where the study had been terminated, correct?
A. Yes, I see that.
Q. Okay. And there are several other entries on the -- one on the next page and one on the following page about study terminated.
Do you see that?
A. Yes.
Q. And that means the study was not finished, correct?
A. I believe that's what that means,

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yes.
Q. Okay. And there are a number of entries that do not list a publication source for the studies listed in this document, correct?
A. That's correct.
Q. Okay. Put that aside.
(Document marked for identification as Exhibit Purdue-Fanelli-21.)
BY MS. DICKINSON:
Q. I'm going to hand you what I've marked as Exhibit 21.
Exhibit 21, what we've marked as Exhibit 21 is a memo from April 10, 1995 to the OxyContin Launch Team.
Do you see that?
A. Yes.
Q. And the first or second paragraph, little bigger paragraph ends with a couple statements to the OxyContin launch team that says, "OxyContin's positioning statement is all the analgesic efficacy of immediate-release Oxycodone, with convenient Q12 dosing. The

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proposed features and benefits of OxyContin were listed. The convenience of Q12 dosing was emphasized as the most important benefit."

Do you see that?

A. Yes.

Q. And a large part of Purdue's marketing of its OxyContin product was the Q12 dosing aspect, correct?

MR. SNAPP: Object to the form. Objection as beyond the scope.

THE WITNESS: I'm actually not aware of the -- I wasn't there at the time, but, also, of what the commercial launch campaign was.

Statements such as positioning statements are not -- positioning -- I mean, it's not meant to be a claim, I mean, not meant to appear. It's how plans are designed around those statements, and this is a meeting -- meeting minutes of what was discussed there.

BY MS. DICKINSON:

Q. I don't think we need to belabor

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the point.

Was OxyContin marketed for 12-hour relief?

MR. SNAPP: Objection to form.

THE WITNESS: Of course.

BY MS. DICKINSON:

Q. That was really all I was getting at.

That was a key aspect of the drug's properties in marketing, correct?

MR. SNAPP: Objection, beyond the scope.

THE WITNESS: Again, it's not -- I don't know, you know, was it a key element? It was part of the promotional message.

BY MS. DICKINSON:

Q. You don't know, sitting here today, whether 12-hour relief was a part -- a key part of the marketing messages for OxyContin?

MR. SNAPP: Object to the form. Objection as beyond the scope.

THE WITNESS: It was part of the

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marketing messages, yes.

BY MS. DICKINSON:

Q. And it was a big part, right?

MR. SNAPP: Objection to form.

THE WITNESS: The 12-hour dosing --

MR. SNAPP: Wait, let me get the objection in.

THE WITNESS: Sorry.

MR. SNAPP: Object to the form. Objection as beyond the scope.

THE WITNESS: The extended-release form 12-hour was an important part of the message.

BY MS. DICKINSON:

Q. Okay. Purdue had information in the first few years of OxyContin's sale that the 12-hour dosing didn't work, that patients would have to dose more frequently, correct?

MR. SNAPP: Objection, beyond the scope.

THE WITNESS: I don't know what information Purdue had related to that.

BY MS. DICKINSON:

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Q. Do you know whether Purdue had in its possession a study that was done in 1989 on some of the first patients to use OxyContin in Puerto Rico?

MR. SNAPP: Object to the form.

THE WITNESS: I'm not aware of that.

MR. SNAPP: Did you say '89?

MS. DICKINSON: Yes, that's what it says.

Here, let's make this easier. That's not the right exhibit number. Hold on just a second. Can you tell me what the last exhibit number was?

MR. SNAPP: Twenty-one.

MS. DICKINSON: Twenty-one, okay. Here we go, okay.

(Document marked for identification as Exhibit Purdue-Fanelli-22.)

BY MS. DICKINSON:

Q. I'm going to hand you what's been marked Exhibit 22 and some copies of that.

And Exhibit 22 is a study -- is a

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copy of a double-blind, randomized, single dose, parallel group study bearing the date February 14, 1989.

Do you see that?

A. Yes.

Q. Okay. And have you ever seen this study before?

A. No.

Q. You're not familiar --

A. I don't remember seeing this. This is dated '89. I joined Purdue in 2000. I don't remember this particular document.

Q. But you didn't prepare for the topic 7 regarding the results of any such testing at Purdue for purposes of your deposition today, correct?

MR. SNAPP: Object to the form. I'm not sure this has to do with a Purdue product, first of all.

MS. DICKINSON: He can answer the question.

BY MS. DICKINSON:

Q. You didn't prepare for this topic 7 by reviewing this study and the results for

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the purposes of your deposition today?

MR. SNAPP: Object to the form.

BY MS. DICKINSON:

Q. Correct?

A. I didn't review this document.

Q. Okay. Did you, in preparing to talk about the results of testing at Purdue regarding its opioid products, ever discuss with anyone the results of this study done in Puerto Rico on women who were using OxyContin?

MR. SNAPP: Object to the form. Object as beyond the scope.

THE WITNESS: No, I did not.

BY MS. DICKINSON:

Q. Do you know if in this study more than a third of the women that were given OxyContin started complaining about pain in the first eight hours; do you know?

MR. SNAPP: Object to the form. Object as beyond the scope.

Do you want him to read the study?

BY MS. DICKINSON:

Q. Do you know?

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A. Not without looking at the study.

Q. And you hadn't looked at the study to prepare for today, correct?

A. Correct.

Q. Okay. Do you know if Purdue ever submitted this study to the FDA?

MR. SNAPP: Object to the form. Object as beyond the scope.

THE WITNESS: I do not know. I can't tell from this.

BY MS. DICKINSON:

Q. Do you know if Purdue had information that its OxyContin product was not lasting for 12 hours?

MR. SNAPP: Objection, beyond the scope.

THE WITNESS: What do you mean by "information"?

BY MS. DICKINSON:

Q. Any information, do you know if Purdue at any point in time regarding the original formulation OxyContin product had knowledge that its product was not lasting for 12 hours?

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MR. SNAPP: Same objection.

THE WITNESS: So the approved package insert talks about 12-hour dosing of the product. That's the evidence that was provided in the NDA, and that's what FDA approved.

Individual reports -- obviously, individual patients' response, pharmacological, pharmacodynamic response varies. I don't know if there were reports of -- it would be an adverse event if the drug didn't last that could be reported. Those -- that information would have been reported to Purdue, but I'm not aware of it, specifically, specific cases.

BY MS. DICKINSON:

Q. Okay. So the product OxyContin was approved for 12-hour dosing, correct?

A. Yes.

Q. And you're not aware of Purdue receiving information that OxyContin was wearing off in patients before 12 hours; is that what you're saying?

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MR. SNAPP: Objection, beyond the scope.
THE WITNESS: I'm saying I'm not aware of the specific incidence of that report, that kind of reporting.
BY MS. DICKINSON:
Q. If Purdue received that kind of information, should it have submitted it to the FDA?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: It depends on how it was reported. There are requirements around adverse events, and it has to, you know, raise to that level of a serious adverse event, we would have reported it.
BY MS. DICKINSON:
Q. Would --
A. But, again, depends on the nature of the report.
Q. Are you suggesting that Purdue would only have provided that sort of information if it rose to the level of the

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requirement?
MR. SNAPP: Object to the form. Objection as beyond the scope.
THE WITNESS: We would report issues that were a serious adverse event and deemed so by our pharmacovigilance group.
BY MS. DICKINSON:
Q. And how is something deemed to be a serious adverse event at Purdue?
A. That's under the purview of the pharmacovigilance department. It, you know, review of individual cases, but if a product is not performing as stated in the package insert, that's part -- that would be part of the reporting.
Q. If a product is not performing as stated in the package insert, it would be important to provide any information about that failure of performance to the FDA, correct?
MR. SNAPP: Object to the form. Objection as beyond the scope.
THE WITNESS: Yes, that's correct.

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BY MS. DICKINSON:
Q. Okay. We're going to move on to the next topic, and I hope to do it fairly quickly, and then we'll take a lunch break. That's topic 10.
So if we could pull out the notice again, just real quick, that first exhibit. Topic 10 for which you are identified to testify on behalf of Purdue states, the identification of your, and that's Purdue's, policies and procedures for and the identity of all persons responsible for interacting with the Food and Drug Administration, FDA, the DEA, the US Department of Justice or other state and federal government agencies.
Did I read that topic correctly?
A. Yes, this part.
MR. SNAPP: It's right here.
THE WITNESS: I know but it's not here.
BY MS. DICKINSON:
Q. And are you prepared to testify on that topic today on behalf of Purdue?
MR. SNAPP: Just to be clear,

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he's prepared to testify as to topic 10 as stated in our November 15th filing that I think has been marked as Exhibit 5, if I remember correctly.
BY MS. DICKINSON:
Q. Okay. And, for the record, you are not prepared to testify on topic 10 as written, by statement of your counsel, correct?
MR. SNAPP: Do you want to --
THE WITNESS: Correct.
MR. SNAPP: -- look at the definition and compare them, and you'll see that they're incredibly similar.
MS. DICKINSON: Fair enough.
BY MS. DICKINSON:
Q. I'm asking, though, are you prepared to talk -- prepared today to testify on topic 10 for Purdue as written?
A. I'm prepared with the minor modification.
Q. So the answer is, no, you're not prepared to testify as written in topic 10, correct?
A. Correct.

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Q. Okay. All right. What is the minor modification that your counsel has made to topic 10 in the objections that are marked as Exhibit -- I'm sorry.

MR. SNAPP: Five.

BY MS. DICKINSON:

Q. Five.

A. The exclusion of other state and federal government agencies.

Q. Okay. So you are not here prepared to testify on behalf of Purdue as to that portion of the topic, correct?

A. Correct.

Q. Okay. Let's take the policies and procedures for interacting with the FDA first.

Do you have a list of the policies and procedures that exist at Purdue or have existed at Purdue from 1995 to present regarding interacting with the FDA?

A. Yes.

MS. DICKINSON: Okay. Can we mark that list. First, I'm sending it around. Can we mark the list as Exhibit

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23.

(Document marked for identification as Exhibit Purdue-Fanelli-23.)

BY MS. DICKINSON:

Q. A very helpful list, thank you.

Okay. We've marked as Exhibit 23 what I believe to be the Purdue's answer to topic 10 with respect to the FDA and the DEA; is that correct?

A. Yes.

Q. Okay. Topic -- or Exhibit 23 identifies it looks like four policies and procedures for interacting with the FDA at Purdue.

Do you have copies of those policies and procedures with you as well?

A. Yes.

MS. DICKINSON: Okay. Could we maybe mark those? If I could get a copy of all of those four policies, that would be helpful. Do you have those coming?

MR. SNAPP: Do you want to pass

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the exhibit stickers over?

MS. DICKINSON: Sure, that might be --

MR. SNAPP: That might be easier, yeah.

MS. DICKINSON: I'm going to pass them, not throw them. You can pass them back.

So we're starting with 24 for the first one, okay. I'm sorry, here's 24, coming around.

(Documents marked for identification as Exhibits Purdue-Fanelli-24 through 27.)

BY MS. DICKINSON:

Q. Okay. Let's just take -- and we're talking again about the policies and procedures that exist at Purdue for interacting with the FDA first.

And the first one of those that Purdue has identified is Exhibit 24; is that right?

A. Yes.

Q. Okay. And what is Exhibit 24?

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A. It describes a standard operating procedure for interacting with FDA regarding an NDA or a ANDA or supplemental new drug application.

Q. Okay. And is this the policy that is in place currently today?

A. Yes.

Q. Okay. Was there a previous policy similar to this policy?

A. Yes, this is version, as it says in the back, 4.0, so this procedure has been in effect.

Q. How -- I assume there's a 1.0, a 2.0 and 3.0; is that right?

A. I'm assuming as well, but I'm not -- I don't -- yes, that's how we mark them.

Q. Do you know how far back a policy of this type went at Purdue, i.e., when was 1.0 put into effect?

A. I don't know the exact date. I know that the policies were always in place. I don't know if it was written down as a specific standard operating procedure in this way and how long that was.

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Q. Okay. Do you know when the first time that the policies addressed in Exhibit 24 were written down?
A. No, I don't know the exact date. I know the policy has been in place throughout Purdue's existence.
Q. So whether it was written down or not, the policy that is written down in Exhibit 24 has always been in place at Purdue?
A. Yes.
Q. Okay. And what is the -- I'm sorry. You said that this was the policy that governed Purdue's interactions with respect to the NDA; is that right?
A. This is actually related to the submissions of an NDA.
Q. Okay. Does the policy cover any other topic or subject?
A. This one is about or supplements and talking about that that -- what it's referring to is the federal regulation that we follow in order to file an NDA. That's what this is about.
Q. Okay. The second policy that I

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believe has been marked as Exhibit 25 is --
A. Correct.
Q. -- it says REGSOP0035; is that right? What's Exhibit 25 in front of you? I'm sorry.
A. So the difference -- the first one is an NDA. The second one is about filing an IND.
Q. Okay, sorry. So Exhibit 25 is the second item on your list that was marked as Exhibit 23, and it is the initial IND submission standard operating procedure; is that right?
A. Yes.
Q. And what does this policy cover?
A. It talks about the filing of the initial IND, so the opening of an IND in order to conduct clinical trials.
Q. Okay. And this is the policy that is currently in effect at Purdue, correct?
A. Yes.
Q. And similar to the last policy in Exhibit 24, has the policy, as it's outlined in Exhibit 25, always been the same at Purdue, whether it was written down or not?

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A. Correct.
Q. And do you know when the first written version of this policy was?
A. I do not.
Q. Okay. Exhibit 26, what is Exhibit 26?
A. This talks about submissions of promotional material to FDA.
Q. Okay. And --
A. Advertising and promotional.
Q. Exhibit 26 is the third item on Purdue's list listed on Exhibit 23 in its response to topic 10; is that right?
A. Yes.
Q. Okay. And this is the policy that is currently in existence at Purdue, correct?
A. Yes.
Q. Is it also the same as the other two policies we've talked about, where the information in this policy has always been the policy at Purdue, whether it was written down or not?
A. Correct.

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Q. Okay. And do you have any idea when the first written version of this policy was put into effect?
A. No, I do not.
Q. Okay. Let's talk about Exhibit 27. What is Exhibit 27?
A. So one of the interactions we have with FDA is an advisory committee, and this is a document that describes the processes, roles and responsibilities around responding to an advisory committee or preparing -- preparing for an advisory committee.
Q. Okay. And this policy was or this playbook was -- is dated December 15, 2015; is that right?
A. Yes.
Q. Is this a playbook that's currently used at Purdue?
A. Yes.
Q. And how long has it been used?
A. Well, this playbook was produced in December of 2015. There was no -- nothing written down to this, but similar to the others, these were the procedures that we followed. It

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was after an advisory committee that we had, a project to just provide this information as a guide to how to prepare for another advisory committee.

Q. Okay. And this first time this policy or playbook was committed to writing was in 2015?

A. Correct.

Q. Okay. Do you know similar -- I know on this Exhibit 23 you listed the persons most responsible for interacting with the DEA.

Do you know who the persons most responsible for interacting with the FDA are at Purdue?

A. Yes.

Q. Okay. Who are they?

A. So FDA, you can imagine, there's many, many pharmaceutical companies, many sponsors, so similar practice at both sponsors and FDA is there is one person, and part of my title is FDA liaison, so one person at the company who is the interface with the FDA. That's the person the FDA will call. That's the person that signs the cover letters. Remember I

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said about the forms?

Q. Yes.

A. So those folks reside in regulatory affairs department.

Q. Okay.

A. So it's the -- we call them RAPMs, regulatory affairs project managers or FDA liaisons, so that's the prime person for contact for FDA.

Q. Okay. Has it always been true over, let's say, since 1995 when OxyContin was launched that there was always a primary person for a drug that would interact with FDA?

A. Absolutely.

Q. Okay. And where could I find who those people are for the particular drugs?

A. So any -- if you look in those regulatory affairs, some of those org charts split out. Actually, there's a group that's called FDA liaison or project managers, those are the individuals. And usually, it depends on the history of Purdue, but usually in any documents you look, the person signing the cover letter, so if you look at OxyContin documents,

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you'll see the person on the cover letters and it says regulatory affairs, that's the prime person.

Q. Okay. Great. You don't have a list of the primary people for OxyContin, for example, with you today?

A. We could look at the org charts. I know -- I don't remember in '95, but they're folks like Chris Prue, Beth Conley, and currently it's myself.

Q. When did you take on the primary responsibility of interacting with the FDA with respect to OxyContin?

A. About when Beth Conley left the company, which is only -- it's not a year yet. Beth Conley -- again, looking at that org chart, starting -- well, now in 2014, I'm the head of the entire department.

Before that, for about I think three or four years, I was a head of that entire group. So all those folks reported to me. So I would, again, not be the prime person, but I would be involved in all the conversations or all the interactions.

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Q. Okay. Do you know who the primary person was for OxyContin starting from its launch in 1995?

A. I don't think Chris joined -- when I came, Chris Prue was responsible in 2000. If I could look at that org chart, I could figure out who it was.

Q. Sure, could you quickly. I just want to make sure I understand who the persons are that were responsible for interacting with FDA with respect to OxyContin.

A. You know -- well, I don't know if we have it. It would be on the submission cover letter. Do you have the next one? The big one we were looking at has more detail. In 1995 the head of the group was Jim Conover at that time. He was the head of the group that included some of those individuals.

I'm not sure who the -- if someone reporting to him might have been involved, but I would say Jim Conover is a good -- yeah, this is '95 -- would be involved in all those correspondence.

Q. Are there also sections of the

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company in terms of governmental affairs, you know, sort of the lobbying side of things that interact with the FDA? Do you have that segment of the company at Purdue?

A. There is a group government affairs, but they -- unless regulatory is involved, they are more speaking congressional members, they don't really speak to FDA, per se. Now, there are other individuals outside of regulatory who talk -- like in large groups, so if we have a conference call with FDA, I have one Monday, you know, all the disciplines that that conversation is about would be on a teleconference or go to a meeting. So if we're talking about, you know, a clinical trial, the clinical representative would be there.

But without going through the regulatory department individual, there's not usually direct connection, you know, so they wouldn't call someone in the pharmacokinetics group at FDA without having a person in regulatory, unless that's arranged with FDA.

There are times during a review, FDA may say, go ahead and have your formulation

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guy call mine, you know, that kind of thing, but that's rare.

Q. I'm trying to figure out if, for example, new regulations are being passed or something of that nature --

A. Sure.

Q. -- is there a group at Purdue that would interact from the government relations standpoint with FDA?

A. Yes, yes, they might at a high level.

Q. Who would those folks be?

A. You know, folks in that government relations, but it's rare that -- as I say, they talk to FDA, but there have been conversations with FDA leadership on occasion, not usually the division directors, so the folks dealing with a particular therapeutic class, it's more broad levels where they might be involved.

Q. Okay. Do you know if Purdue hires lobbyists or outside governmental affairs consultants whose job it was to interact with FDA?

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A. I'm not aware of that.

Q. Okay. Let's turn to the interactions with the DEA and the policies with respect to interacting with DEA, okay?

A. Sure.

Q. So you have listed three policies and procedures that exist at Purdue with respect to interacting with DEA on Exhibit 23; is that correct?

A. Yes.

Q. Okay. And one says SOM program SOP, and it lists SOP 000 and then a 17. The other lists the SOP 1.7.1, and the third is an SOP that's 7.1; is that correct?

A. Yes.

MR. SNAPP: Do you want to mark these?

MS. DICKINSON: Well, yes, just a second, though.

BY MS. DICKINSON:

Q. So today we were for the first time provided with SOP 7.7 on "System to Disclose Suspicious Orders of Controlled Substances."

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Is that policy on this list and I'm just not understanding that it is, or is that an additional policy that should be on this list?

A. Could you -- can we take a look?

Q. Sure. I'm going to mark as Exhibit 28.

(Document marked for identification as Exhibit Purdue-Fanelli-28.)

BY MS. DICKINSON:

Q. A copy of what was produced to us this morning for the first time or two days ago, I'm sorry, two days ago, not this morning, by Purdue that is titled SOP, title, "System to Disclose Suspicious Orders of Controlled Substances."

Do you see that?

A. Yes.

Q. Okay. And is that a policy that is on this list that you have in Exhibit 23 of the policies and procedures that exist at Purdue for interacting with DEA?

A. I have to -- if you give me some

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time to look at that, but if you look at the S -- the one that starts with SOM program.
Q. Okay.
A. The purpose of this SOP is to provide guidance on identifying, reviewing, documenting and reporting suspicious orders in compliance with the Controlled Substance Act, so I believe --
Q. Let's mark the other three, then maybe we can go at it that way, and I'll do 7.7 last, how about that? I will hand you around the exhibit stickers. If you wouldn't mind marking the three that are listed on Exhibit 23.
A. Okay. Oh, you have them? Can I keep this one?
Q. Sorry. Which one are we talking about?
A. The one -- 28 you handed me.
Q. So we've marked Exhibit 28, and that's the policy I handed you.
A. Yes.
MS. DICKINSON: But then let's mark the three on your list on Exhibit 23 as 29, 30 and 31, if you would.

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(Documents marked for identification as Exhibits Purdue-Fanelli-29, 30 and 31.)
MR. SNAPP: They're marked.
BY MS. DICKINSON:
Q. Okay. And let's -- can I have copies, 29, 30 and 31.
So let me understand what we've now marked as -- so Exhibit 29 is the first SOM policy on your list; is that right? Has that been marked as the --
A. That is the SOM program, yes.
Q. Okay. So what is Exhibit 29?
A. It's a standard operating procedure to identify, review, document and report suspicious orders in compliance with the Controlled Substance Act.
Q. Okay. And that policy has a release date of September of 2017; is that right?
A. Yes.
Q. And that document version says it's 1.0, so that's the first time such a policy was in writing, correct?

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A. Yes -- well, if I'm looking at this document, which is from Purdue as well, it's similar, but this particular policy, with that identifier, yes, it's the first version.
Q. Okay. So the first version of a policy for identifying, evaluating and reporting suspicious orders as set forth in Exhibit 29 was done on September 25th, 2017, correct?
MR. SNAPP: Object to the form.
THE WITNESS: It appears there were policies prior to this, but this is the current policy, as stated.
BY MS. DICKINSON:
Q. Okay. And you're here today to testify about the policies that existed at Purdue with interacting with DEA, and I just want to make sure I'm getting the full range of those policies as they exist.
You have three listed on here, and that list did not include what I handed and marked to you that we received two days ago as Exhibit 28; is that correct?
A. That is correct.
Q. Do you know why Exhibit 28 wasn't

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provided to you or that you didn't provide it on this list?
A. I do not know.
Q. Okay. How did you go about collecting the policies that are on this list?
A. They were collected by interacting with -- we have -- especially with interacting with DEA as the question, the folks that are listed there are responsible for that. It doesn't reside in regulatory affairs, so we reached out to them for -- and to our law colleagues for the policies that are related to that.
Q. Who was actually the person that collected and gave you the policies?
A. I'm not -- I don't know who the exact person is.
Q. Okay. Do you know how you received them?
A. I think our colleagues at Dechert reached out to our law group.
Q. Okay. And you received this list from --
A. In preparation.

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Q. -- your lawyers?
A. Yes.
Q. Okay. And that list does not include the policy that was produced to us two days ago that is marked as Exhibit 28, correct?
MR. SNAPP: Object to the form.
THE WITNESS: Correct.
BY MS. DICKINSON:
Q. Okay. So we've talked about Exhibit 29.
What is Exhibit 30?
A. This is a procedure that resides in the law department, and it relates to a program, we refer to it as the ADD program, and that's how it's listed on your list there, to look at concerns around abuse and diversion, if there are observations related to that. It details assessment of that and reporting of it.
Q. Okay.
A. And how it gets to DEA.
Q. And the date on this policy is September 2015, correct?
A. Yes.
Q. And it says it supersedes a

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June 2007 policy, correct?
A. Yes.
Q. Okay. And so this policy, is it safe to assume, was in effect from 2007 to 20 -- or to the present? Or I'm sorry, I'm sorry, that's not at all correct.
This policy was in effect as of 2015 going forward, correct?
A. This particular one, yes.
Q. Okay. And there was a separate policy that was in effect from June of 2007 to 2015, correct?
A. Correct, an earlier version.
Q. Okay. Do you have the earlier version with you?
A. I do not.
Q. Okay. Do you know if there was an earlier version earlier than 2007?
A. I do not know.
Q. So you're not here prepared to testify on any of the policies prior to 2015 with respect to interacting with the DEA regarding the abuse and diversion detection program; is that right?

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MR. SNAPP: Object to the form, misstates prior testimony. He's here -- beyond the scope.
MS. DICKINSON: Let the witness testify, please.
MR. SNAPP: I am.
BY MS. DICKINSON:
Q. Are you here to testify about the abuse and the diversion detection program prior to 2015?
A. Yes.
MR. SNAPP: Object to the form.
BY MS. DICKINSON:
Q. Okay. But yet you don't have the written policies with you?
MR. SNAPP: Object to the form, calls for -- beyond the scope.
THE WITNESS: That's correct.
BY MS. DICKINSON:
Q. Okay. So when -- I'm a little unclear as to how you're going to testify about the policies if we don't have them to look at.
MR. SNAPP: Object to the form.
THE WITNESS: I'm aware of the

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policy, I just don't have the written documentation of those exact policies.
BY MS. DICKINSON:
Q. And is the policy or was the policy prior to 2015 identical to the one we're looking at here on Exhibit 30?
MR. SNAPP: Object to the form, beyond the scope.
THE WITNESS: It was consistent with this policy. I don't know if it's identical in every way.
BY MS. DICKINSON:
Q. And we don't know because we can't look at it here, as we're sitting here today, right?
MR. SNAPP: Object to the form. Can we take a break after this question, please.
THE WITNESS: We don't have it, yes.
MS. DICKINSON: Okay, I have about ten more minutes probably on these topics. Do you want to keep -- do you really want to take a break, or do you

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just want to do ten minutes? I mean --
MR. SNAPP: No, I want to take a break.
MS. DICKINSON: Okay. Well, then we might as well take a lunch break.
MR. SNAPP: We've been going for an hour and 15 minutes.
MS. DICKINSON: Well, no, I'm just trying to get to a normal stopping place. I have about 10 minutes. I mean, we can do the --
MR. SNAPP: I understand, but I think we should take a lunch break at this point. We've been going for 75 minutes.
MS. DICKINSON: Okay, fair enough. Take a lunch break. Come back on topic 10.
THE VIDEOGRAPHER: Remove your microphones. The time is 12:58 p.m. Going off the record.
(Luncheon recess.)
THE VIDEOGRAPHER: The time is 1:47 p.m., back on the record.

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BY MS. DICKINSON:
Q. Dr. Fanelli, we're back on the record. I just wanted to go through a couple things on topic 10 before we leave that topic.
Topic 10 asks for identification of Purdue's policies and procedures regarding interacting with the DEA for the time period 1990 to present.
Is that your understanding of the topic that you were supposed to provide testimony on today?
MR. SNAPP: Object to the form.
THE WITNESS: My understanding was that we would be discussing those policies and procedures, yes, during that time frame, not presenting, you know, handing them, but discussing them, yes.
BY MS. DICKINSON:
Q. Okay. So your understanding was that we were going to discuss the policies and procedures but not necessarily look at the physical documents from 1998 to present?
A. Correct.

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Q. Is that correct?
MR. SNAPP: Object to the form.
BY MS. DICKINSON:
Q. Okay. Are you here today prepared to identify all policies and procedures at Purdue from 1990 to present for interacting with the DEA?
MR. SNAPP: Object to the form.
THE WITNESS: No.
BY MS. DICKINSON:
Q. Okay. What portion of that topic are you prepared to address?
A. I can address the individuals and the policies and procedures that were in place for reporting to the DEA. I don't have the specific SOPs of those.
Q. Okay. So you're not here prepared to give the corporation's answer identifying the universe of the SOPs that have existed for interacting with the DEA at Purdue? That's what I'm trying to get at.
A. Okay.
MR. SNAPP: Object to the form.
THE WITNESS: I can describe the

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procedures that were involved and the individuals who report to DEA. I don't have the document, you know -- as we talked before, some of our procedures are not written down in documents or I don't have them, you know, the specific writing -- write-up of those procedures.
BY MS. DICKINSON:
Q. What did you do to prepare for this topic?
A. I spoke to Mark Geraci, who is the head of our corporate security, about these policies and reviewed the documents that we presented.
Q. And those are the three documents that are listed on Exhibit 23?
A. Yes.
Q. And what did you talk to Mr. Geraci about?
A. The specifics of those policies. As we talked before, regulatory affairs doesn't deal directly with the DEA, that's Mark, the corporate security is the lead interaction with DEA. When there are inspections in our

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facilities, manufacturing facilities, that's folks like Monte Phipps, our technical -- you know, the technical folks that's on your list, and Gwen Mack is related to diversion control, monitoring of shipments and those kinds of things. Anyway, those individuals are the ones that we talked to, and Mark and I look -- discussed those SOPs as well.

Q. Okay. How long was your conversation with Mr. Geraci?

A. I don't recall. It was on a one day. It didn't last a whole day.

Q. More or less than an hour?

A. Approximately an hour, I would think, but I don't recall so much.

Q. I'm not sure if we marked the policy, the SOP 7.7, the one that we got two days ago, the 031.

A. I have it.

Q. Had we marked that? Okay. What number did we mark that as?

A. Twenty-eight.

Q. Okay. And this policy was not provided to you by Mr. Geraci, was it?

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A. No.

Q. Okay. Did you discuss this policy with Mr. Geraci?

A. It appears that this talks about suspicious order, which we have one of the policies that I handed you. I'm not -- I can't say for sure, but I think it's related to -- well, it is definitely related to the same procedure, so we did talk about that.

Q. Can -- what I'm trying to get a handle on is when was the earliest date that Purdue had a suspicious order monitoring policy? And this one is dated 3/12/03, was that the first time that Purdue had a suspicious order monitoring policy?

A. I'm not aware of the day it started, the date it started. There clearly was one at this point, '03.

Q. Okay. And you don't know -- you're not prepared here today to answer the question of whether Purdue had a written policy on suspicious order monitoring prior to '03; is that right?

A. That's correct.

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Q. And this document that we produced to you at the deposition, in number 4 identifies a "Procedure for Customer Service."

Who is customer service?

A. It's part of -- it's a department within Purdue that it's in the sales and operations group who responds to customer requests.

Q. Okay. This procedure for customer service says, "They review each other for unusual quantifies or any other deviation from the customer's regular order pattern."

Do you see that?

A. Yes.

Q. Is there an SOP, a standard operating procedure, for how customer service goes about this?

A. I don't know if there's an SOP. I'm looking at our --

Q. You don't know?

A. The details are not in that particular document.

Q. And do you know if the details exist in a document at Purdue?

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A. If you look at the one with the reference 29, that the -- which is the one I believe it's a similar topic -- well, it is similar topic as that, there's a procedure in terms of review, procedure number 1.

Q. And Exhibit 29 is the policy that went into effect in September of 2017; is that right?

A. Yes.

Q. Okay. For suspicious order monitoring we have Exhibit 28, we have Exhibit 29, which is dated September 25th, 2017. We have Exhibit 31, which is dated February 29, 2016.

Are these three policies the universe of Purdue's policies with respect to suspicious order monitoring?

MR. SNAPP: Objection, beyond the scope.

THE WITNESS: I'm not aware if there are other procedures.

BY MS. DICKINSON:

Q. Okay. When you talked with Mr. Geraci about the procedures that exist with

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respect to interacting with the DEA, did you talk about the universe of the specific procedures and policies that exist? Was that one of the topics of that conversation?

A. That conversation was about the individuals who interact with the DEA and how information is exchanged with the DEA.

Q. It was not about the policies and procedures, correct? That topic, the policies and procedures was not the topic of your conversation with Mr. Geraci; is that correct?

A. We talked about the procedures and the policies, but not the -- you know, specifically if we had all the particular SOPs.

Q. Okay. I'm trying to figure out how I find out from you what the universe of the SOPs is with respect to interactions with the DEA.

Are these documents that we've marked as between Exhibit 28 and Exhibit I think it's 31, is that the universe of the written policies and procedures for interacting with the DEA at Purdue?

A. I believe it covers the -- all

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the policies that deal with interacting with the DEA. I'm not aware if there may be other procedures. As we -- there are cases where subparts for particular departments and I may not be aware of those.

Q. Okay. So you're not prepared to address the topic in its entirety about the policies and procedures for interacting with the DEA; is that correct?

MR. SNAPP: Object to the form.

THE WITNESS: I'm prepared to as -- to talk about the policies and procedures, but you're correct, I don't have the -- I'm not aware if I have the whole universe of all those policies.

BY MS. DICKINSON:

Q. And you're not aware so you can tell me what that universe is, right?

A. Correct.

Q. Okay. I'm going to hand you what has been marked as -- I'm going to hand you what's been marked as Exhibit 32.

(Document marked for identification as Exhibit

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Purdue-Fanelli-32.)

BY MS. DICKINSON:

Q. Exhibit 32 appears to be one of the earlier versions of the policy that you did bring with you today, which is SOP 1.7.1; is that right?

A. Correct.

Q. Okay. So there was a policy that we now just marked as Exhibit 32 that existed prior to the policy that you brought with you today from 2015; is that right?

A. Yes.

MS. DICKINSON: And I'm going to mark another policy as Exhibit 33.

(Document marked for identification as Exhibit Purdue-Fanelli-33.)

BY MS. DICKINSON:

Q. And Exhibit 33 appears to be another version of the 1.7.1 policy that we just looked at, earlier version; is that right?

A. Yes.

Q. And you likewise did not review this version of the policy in preparation for

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your testimony today or bring it with you; is that right?

A. Correct.

Q. Okay. And that's dated November 1st, 2002.

Do you see that?

A. Yes.

Q. And do you know today whether there is an earlier version of this policy, earlier than 20 -- or 2002?

A. I do not know.

Q. Okay. I'm going to quickly ask you a few questions about topics 37 and 38 before we go back to topic 30 quickly.

A. Sure.

Q. So topics 37 and 38 on Exhibit 1, Topic 37 is your coordination, your being Purdue, or communications with any defendant in this action, including but not limited to your participation in any industry groups or professional societies or any defendant in this matter as a member, referring to pain care, the sale of opioids, the marketing or promotion of opioids, regulations, rules or laws affecting

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the sale, promotion and marketing of opioids and the potential for abuse and diversion of opioids.

You are not here today prepared to testify on that entire topic, correct?

A. Correct.

Q. And in reading your counsel's responses to the topic, your counsel has designated Alan Must as the person who will provide testimony regarding industry groups or professional societies relating to pain care or opioids. You will not be providing testimony on that subject, correct?

A. Yes, that's correct.

Q. Topic 38, the nature and scope of any meetings, correspondence, communications, documents, contracts or agreements between you and Cephalon, Janssen, Endo, Mallinckrodt concerning the manufacture, development, formulation, marketing, advertising and the sale of opioids or opioid products.

You will not be providing testimony on that entire topic; is that correct?

A. Yes.

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Q. Okay. And for this topic Purdue has not designated another witness; however, they have said that you, Richard Fanelli, would provide testimony regarding communications between Purdue and any other opioid manufacturers, including, as applicable, Cephalon, Janssen, Endo or Mallinckrodt concerning postmarketing studies relating to opioid medications.

So you have only prepared for this topic as it relates to postmarketing studies; is that right?

A. Correct.

Q. And that is also true for topic 37, you have only prepared for that topic as it relates to postmarketing studies; is that right?

A. Correct.

Q. Okay. Is Purdue currently working with other companies to conduct a postmarketing study?

A. Yes.

Q. Okay. What are they doing?

A. There are -- we talked about this briefly earlier. There are postmarketing

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required studies by FDA that are part of the FDA amendment act. FDA now can require postmarketing studies when they believe safety questions have arisen, they want additional studies, so we're working with -- it's varied over time, now there's 12 companies, the ones you mentioned are included, to design, conduct and report those studies.

Q. Okay. And what is the subject of those postmarketing studies?

A. So it's related to misuse, abuse, addiction, overdose and death related to prescription opioid and prescription -- in patients taking prescription opioids and when -- if you look at the first five years ago, the letter from FDA, there were five studies. There are currently 11 studies conducted based on input, public meetings, protocols back and forth with FDA, scientific advice, and now we have 11 studies.

Q. Are you personally involved in that effort?

A. I am -- there are 11 studies, ten of those are observational studies using

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epidemiological data. I am the regulatory lead from -- for all the companies -- the FDA liaison to the FDA for those -- ten of those studies.

I'm also Purdue's representative, along with Marcelo Bigal, it's changed over time, but Purdue's representative on the steering committee as part of the -- I was going to say OPC, the opiate postmarketing required consortium.

Q. Is that what the committee or the group working on that is called?

A. Yeah, yes. Both FDA -- both FDA and the group refer to it -- the opiate postmarketing required consortium.

Q. And are these the studies the FDA required?

A. Yes.

Q. These were the studies we talked about earlier in your deposition?

A. Yes, they are.

Q. Okay. Are there any other postmarketing studies that you were working with the entities identified in these topics on?

A. No.

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Q. Okay. We can go back to topic 30 briefly, and if you would look at topic 30, Exhibit 1, please.

Topic 30 reads warning letters sent to you, that's Purdue, by the FDA and the DEA regarding your marketing of your opioid products, response to these letters, all subsequent actions you took in response to those communications and all budgets for any such actions by year.

Are you prepared to testify on that topic on behalf of Purdue?

MR. SNAPP: Just for the record, Dr. Fanelli has been designated by Purdue to testify on topic 30 as stated in our November 15th supplemental responses and objections, where we defined his testimony as warning letters sent to you by the FDA and the DEA regarding your marketing of your opioid products, your response to these letters, all subsequent actions you took in response to those communications and all budgets for any such actions by

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year. I'm sorry, I read the wrong thing.

He's prepared to testify on warning letters sent by the FDA or DEA regarding Purdue's marketing of its opioid medications and Purdue's response to an action taken in response to the letters. My apologies. I was reading the wrong thing.

BY MS. DICKINSON:

Q. Okay. So you are not here today prepared to testify on topic 30 as written in Exhibit 1; is that correct?

MR. SNAPP: Object to the form.

THE WITNESS: Yes.

BY MS. DICKINSON:

Q. And you are not going to be providing information on the budget for the responses to the warnings from FDA, correct?

A. That's the part I'm prepared to speak about all of it except for the budgets by year. It's not part of my responsibility, budget.

Q. And you didn't -- to prepare for

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the deposition, though, you didn't ask, even though it wasn't part of your own personal responsibility, you didn't ask anyone else at the company about the budgets for the responses to the FDA warnings; is that right?

MR. SNAPP: Object to the form.

THE WITNESS: That's correct.

BY MS. DICKINSON:

Q. Were you told not to?

MR. SNAPP: Object to the form. I'm going to instruct you not to answer to the extent the question calls for any attorney-client privilege communications, any communications between you and a lawyer.

BY MS. DICKINSON:

Q. Can you answer the question?

A. I can't answer that question.

Q. But, for the record, nonetheless, Purdue is not providing a witness or has not identified one in response to topic 30 on the budgets for the responses to the DEA -- or the FDA warning letters?

MR. SNAPP: And, for the record,

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the plaintiffs have known that since November 15th and never picked up the phone or sent an e-mail to meet and confer on that issue.

BY MS. DICKINSON:

Q. All right. Let's take the warning letters.

MS. DICKINSON: Where did we end up on exhibits. I think we're on 32; is that right? Thirty-three was the last one?

(Document marked for identification as Exhibit Purdue-Fanelli-34.)

BY MS. DICKINSON:

Q. I'm going to hand you what has been marked as Exhibit 34. Exhibit 34, is that an FDA warning letter?

A. Yes, it is.

Q. And what's the date on the stamp on that letter?

A. November 20th, 1996.

Q. Okay. And this warning letter concerns the Purdue Frederick Company's

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promotional materials for the marketing of MS Contin; is that right?
A. Yes.
Q. And does this appear to be a true and correct copy of the warning letter that was sent to Purdue by FDA?
A. Yes.
Q. Okay. FDA in that letter says in the middle of the first paragraph, "We have concluded that Purdue is disseminating promotional materials for MS Contin that contain statements, suggestions or implications that are false or misleading in violation of the Federal Food, Drug and Cosmetic Act, Section 21 USC 352(a) and 331(a) and applicable regulations."
Do you see that?
A. Yes.
Q. That's what FDA was saying in its letter about MS Contin in 1996; is that right?
A. Correct.
Q. Let's turn to the page 3, and there's a section called "Repetitive Conduct," and in that section FDA says to Purdue, "dissemination of these materials represents a

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repetitive course of violative conduct by Purdue in the promotion of MS Contin."
Do you see that?
A. Yes.
Q. And that is what -- that is what FDA told Purdue in November of 1996, correct?
A. Yes.
Q. This section identifies one, two, three, four -- five other letters and a meeting with FDA between 1993 and 1994 on this subject, correct?
A. Yes, letters and a meeting, yes.
Q. Do you know what the response by Purdue was to that warning letter?
A. I do not.
Q. Okay. You can put that one aside. So just to clear up, I just asked you if you knew what the response was. You did not investigate or were not provided with any information regarding the response to this warning letter in preparing to testify on topic 30 about the warnings sent to Purdue by the FDA and the responses; is that right?
MR. SNAPP: Object to the form.

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THE WITNESS: Correct.
BY MS. DICKINSON:
Q. Okay. I hand you what's been marked as Exhibit 35.
(Document marked for identification as Exhibit Purdue-Fanelli-35.)
MS. DICKINSON: Oh, there's copies here. Sorry. Just a minute. Did I hand you the folder with the copies? I'm sorry.
THE WITNESS: Yeah.
MS. DICKINSON: It came your way. All right. I'm sorry.
BY MS. DICKINSON:
Q. Okay. Exhibit 35 is what?
A. It's a untitled letter to Beth Conley regarding OxyContin.
Q. And the date on that is May 11th, 2000; is that right?
A. Correct.
Q. Okay. Did you review this document in preparation for your topic on topic 30?

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A. Yes.
Q. Okay. And in the first paragraph FDA is telling Purdue that as part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications has identified an advertisement for OxyContin tablets, disseminated by Purdue that violates the federal drug -- Federal Food, Drug, and Cosmetic Act and its implementing regulations.
Do you see that?
A. Yes.
Q. And it has two sections entitled "Misleading Efficacy Presentation" and "Misleading Safety Presentation."
Do you see that?
A. Yes.
Q. Okay. And was there a written response to this letter?
A. Yes.
Q. Okay. Do you have that with you today?
A. I believe so.
Q. And while your counsel is

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looking, this letter dated May 11th, 2000, that is a true and accurate copy of a communication from the FDA to Beth Conley at Purdue Pharma, correct?

MR. SNAPP: Object to the form.

THE WITNESS: I believe it is, yes.

MR. SNAPP: Are you going to show him a second untitled letter from May of 2000 also?

MS. DICKINSON: I don't know, because it's sort of his job to identify how many there were. I think I only have this one. If there's another one, we might as well get it out. I'd like to mark all the warnings, if possible.

MR. SNAPP: This isn't a warning letter. It's an untitled letter.

MS. DICKINSON: If you could give me a copy, that would be great.

MR. SNAPP: Absolutely. I'll send one over your way.

THE WITNESS: Do we have the stickers?

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MS. DICKINSON: Do you guys want the stickers? Here, to make this go faster, can we get a stack of the letters he did review to prepare for this?

MR. SNAPP: That's exactly what I'm doing. You got it.

MS. DICKINSON: That would be helpful.

MR. SNAPP: Absolutely.

MS. DICKINSON: We're going to mark as Exhibit 36 -- this is 35.

MR. SNAPP: I think we're on 36.

MS. DICKINSON: We're on 36.

(Documents marked for identification Exhibits Purdue-Fanelli-36, 37 and 38.)

BY MS. DICKINSON:

Q. Okay. Mr. Fanelli, are you ready?

A. Yes.

Q. Okay. We marked 35, and then the question was what was the response, the written response, if there was any, to Exhibit 35, so

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what was the written response?

A. So Exhibit 36 shows that four days later, FDA sent another untitled letter where they say they've changed their opinion, so they provided other information related to the misleading efficacy. Do you see it there?

Q. And is Exhibit 36 the letter that --

A. It's to Beth Conley.

Q. To Beth Conley, okay, so Exhibit --

A. The same.

Q. -- 36 is a document that has Bates stamp PPLPC005000006728; is that right?

A. Correct.

Q. All right. And that is another communication from FDA to Beth Conley; is that right?

A. That's correct.

Q. And were there -- was there a response by Purdue in between the time of the letter that we just looked at in Exhibit 35 and the letter that got sent in Exhibit 36?

A. Not a formal response.

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Q. Was there an informal response?

A. Not a response to the -- to the issues. There...

Q. Were there interactions with the FDA on Purdue's behalf in between Exhibit 35 and Exhibit 36?

A. I believe there may have been, but I'm not aware on this particular issue. I know it resulted in Purdue response that's in Exhibit 37.

Q. So you don't know if anyone at Purdue in between Exhibit 35 and Exhibit 36 communicated with FDA; is that right?

A. That's correct.

Q. And Exhibit 37 is a true and correct copy of a letter to Spencer Salis at FDA; is that right?

A. Correct. That's the --

Q. And that's from Beth Conley?

A. Yes.

Q. Okay. And was this the written response to Exhibit 35 and 36?

A. Yes.

Q. Was there any other response that

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we haven't already talked about to Exhibit 35 and 36?
A. No.
Q. All right. Put that one aside.
A. Written response, yeah. This one?
Q. Okay. I was going to go next to a 2002 -- or, actually, it's been referred to as a January 2003 warning letter.
Are there any other warning letters that you reviewed, in preparation for this topic, prior to 2002?
A. No, that's the one I'm thinking of.
Q. All right.
A. I looked at one.
Q. Let's take a look.
A. That's the only one I'm aware of.
Q. Okay. I'm going to mark as Exhibit 39 -- 38 disappeared on me.
MR. SNAPP: Thirty-eight is the FDA's response.
MS. DICKINSON: Okay, got it. All right. I'm going to mark as Exhibit

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39, this.
THE WITNESS: Thirty-eight was FDA's acknowledgment of our response.
MS. DICKINSON: Got it.
(Document marked for identification as Exhibit Purdue-Fanelli-39.)
BY MS. DICKINSON:
Q. Take a minute, if you would, and review Exhibit 39. And what is Exhibit 39?
A. Thirty-nine is a warning letter sent to Purdue on December 24th, 2002.
Q. Christmas Eve?
A. Faxed on Christmas Eve.
Q. Okay. And this is a true and correct copy of that warning letter that was sent to Purdue and was addressed to Michael Friedman; is that correct?
MR. SNAPP: Object to the form.
THE WITNESS: It's a copy of the fax that was sent, yes.
BY MS. DICKINSON:
Q. Okay. And Mr. Friedman, he is -- was he an officer of Purdue at the time?

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A. Yes, he was chief operating officer at the time.
Q. Okay. And he is no longer an officer at Purdue, correct?
A. That's correct.
Q. Mr. Friedman is one of the individuals who pled guilty in the US Department of Justice case; is that right?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: That's correct.
BY MS. DICKINSON:
Q. Okay. And this is another warning letter from the FDA like the one we looked at a few minutes ago; is that right?
MR. SNAPP: Objection.
THE WITNESS: No -- sorry.
MR. SNAPP: Go ahead.
THE WITNESS: This is the only warning letter. The letter -- prior letter was an untitled letter. You notice it doesn't have warning written on the top.
Untitled letters go to -- we

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talked about project managers, regulatory project managers. So untitled letters, you notice it went to Beth Conley, she's -- we talked about that she signs the letters and so forth so -- but when FDA determines a warning letter, they're writing a warning letter, that goes then to a higher official in the company, and that's why -- so this is the warning letter.
BY MS. DICKINSON:
Q. Okay. And that warning letter states in the first paragraph, "The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed these advertisements and concluded that they are in violation of the Federal Food, Drug and Cosmetic Act."
Is that correct?
A. Yes.
Q. And that's 2003, when OxyContin had approximately been on the market for seven years at that point, correct?
A. Approximately.
Q. Okay. Do you have the written

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response --
A. Yes.
Q. -- to this warning letter?
Is the written response the letter dated January 24th, 2003? Okay.
A. Yes, it's part of the correspondence.
MS. DICKINSON: All right. It looks like we're going to mark a series of exhibits here. Okay. I'm going to hand you...
MR. SNAPP: He's got a set that's identical to your set. Do you want us to mark over here?
MS. DICKINSON: That would be great. Let's do that.
THE WITNESS: Are we starting with 40?
MS. DICKINSON: Yep. You know what, this one I'll give you 40 and then the rest, if you can mark the rest after that.
THE WITNESS: Okay. When we talk about them, make sure we have the

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same --
MS. DICKINSON: Do you have another copy of 40 or can I have the clean copy from him?
MR. SNAPP: What's the date on 40?
THE WITNESS: I have 40. That's 40. You want to mark so we have the same ones. There's more than this.
(Documents marked for identification as Exhibits Purdue-Fanelli-40 through 46.)
BY MS. DICKINSON:
Q. And we were just talking about the response to the warning letter that Purdue received from FDA that we had marked -- I'm sorry, what was the warning letter that was?
A. Thirty -- sorry.
Q. What exhibit was the warning letter?
A. Thirty-nine.
Q. Okay. That we had marked as Exhibit 39.
And Exhibit 39, if we could go

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back to that for just one minute.
A. Yeah.
Q. At the bottom of the first page, the FDA is telling Purdue that your advertisements thus grossly overstate the safety profile of OxyContin, by not referring in the body of the advertisement to serious, potentially fatal risks associated with OxyContin, thereby potentially leading to the prescribing of the product based on inadequate consideration of risk.
Do you see that?
A. Yes.
Q. Okay. Turn to page 5, please, of that letter. At the top, the first big paragraph, the last sentence, FDA is telling Purdue that "This implication is false or misleading and raises significant public health and safety concerns."
That's what FDA was telling Purdue in this warning letter, correct?
MR. SNAPP: Object to the form.
THE WITNESS: This is at the end of a discussion of minimization of risk

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and information perceived, and that's the conclusion to that part.
BY MS. DICKINSON:
Q. Okay. And then now let's talk about the response. Go ahead.
A. Similar to the untitled letter, the FDA reissued the warning letter after a telephone conversation, and that's what the document in between is, and Purdue.
So the January 14th is a letter to Tom Abrams, who is the head of DDMAC, and Dan Troy, chief counsel at FDA, written by outside attorneys for Purdue, and it documents some of those discussions.
Q. And that's marked as Exhibit?
A. 40.
Q. 40?
A. 40. And then --
Q. Okay. So on January 14th, after receiving the warning letter, Purdue's outside counsel wrote a letter in response to DDMAC dated January 14th, 2003, and Exhibit 40 is that letter; is that right?
A. That's what the letter is. There

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was a meeting, a conversation prior to that. I don't have the exact date of that.
Q. Who was at that meeting?
A. I don't have the attendees at that either at this point.
Q. So you were unaware of the attendees at a meeting to address the warning letter that we marked as Exhibit 39; is that right?
A. Correct.
MR. SNAPP: Object to the form.
BY MS. DICKINSON:
Q. Who would know the answer to that question, who the attendees were?
A. This was in 2000. It would be in our records. We could find out.
Q. In preparing for your testimony on the response to warning letters in topic 30, did you ask anyone who was in attendance at those meetings, or did you look at your records to find out who was in attendance at those meetings?
A. I did not look for that.
Q. All right. Let's move on.

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What was the next event in the response to the warning letter that is Exhibit 39?
A. Forty-one is the reissue of that letter to Purdue from FDA. It's very similar, but has some changes.
Q. Okay.
A. And the response is, I think you mentioned it, January 24th.
Q. Yes.
A. Constitutes the detailed response.
Q. So what you've marked as Exhibit 42 --
A. Uh-huh.
Q. -- is the detailed response on behalf of Purdue to the FDA's warning letter, and this response is dated January 24th, 2003; is that right?
A. Correct.
Q. This response is -- looks like has a three-page cover letter and then a 15-page detailed response with five exhibits; is that right?

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A. Correct.
Q. And does that response accurately -- this exhibit we marked as Exhibit 42, accurately summarize Purdue's positions in response to the FDA's 2003 warning letter?
A. Yes.
Q. Okay. What was the next event in the sequence of the response to the warning letter marked as Exhibit 39?
A. Let's look at the dates. Purdue's response is January 24th, and Exhibit 43 is a letter from Tom Abrams, head of DDMAC, back to Michael Friedman.
Q. Okay. And that letter acknowledges the receipt of Purdue's response, right?
A. Yes.
Q. Okay. All right. What was the next event in the sequence of the response to the FDA's warning letter that was Exhibit 39?
THE WITNESS: Are these in order?
MR. SNAPP: Mm-hmm.
THE WITNESS: On -- looking for the date. Oh, here it is, January 28th,

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so this is January 24th, a letter was sent from Tom Abrams and Daniel Troy to the outside counsels, Richard Morey and Peter Mathers responding to their response providing information.
BY MS. DICKINSON:
Q. And that is what exhibit?
A. Forty-four.
Q. And is there a date on that letter?
A. I think I said, January 28th, 2003. Well, it's a fax, I don't see a date.
Q. Understood. All right. What was the next event in the sequence of the responses to FDA's warning letter that we marked as Exhibit 39?
A. There is a -- responses to FDA?
Q. What was the next event in the sequence of the responses? We were talking about the response --
A. Correct.
Q. -- to that warning letter.
Is there anything else other than the exhibits that we've marked and the meeting

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that you talked about that were part of the response to the warning letter?
A. There was discussion about a corrective ad to be placed in journals that's mentioned in those letters, and Exhibit 46 is a -- there was conversations with FDA about that and, you know, that letter talks about, and it was -- an example was sent to FDA for their review.
Q. Okay. And this corrective ad, was it run in this form?
A. I believe so.
Q. And do you know who it was distributed to?
A. There was a list in the response of the publications.
Q. Okay. And do you know which response it was -- the list is contained?
A. It was produced the 24th, I believe. Let me check. Sorry, I'm out of order now.
There it is. I guess I don't have that list. I thought it was part of this, but it's not.

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Q. Okay. And then what was -- anything else that we've not talked about in the sequence of the response to the warning letter of 2003?
A. The Exhibit 45 is a note to the sales force about a response not to use any materials, prior materials until revised ones were produced.
Q. And how did Purdue ensure that that happened, that the sales reps were not using prior materials?
A. That's part of the compliance group we talked about earlier, they monitor sales force activity.
Q. How did they go about doing that? Is there a written policy for doing that?
A. I'm not aware of those policies.
Q. Do you know how they went about monitoring that the sales force did not -- no longer distributed these materials that are referenced in Exhibit 45?
MR. SNAPP: Objection, form. Objection, beyond the scope.
THE WITNESS: No, I'm not aware

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of the specific policy how those are -- how that occurred.
BY MS. DICKINSON:
Q. Do you know what the process was for redoing the promotional and marketing materials that arose -- that's being mentioned in this memo?
A. Yes.
Q. Okay. What was it?
A. We have a process for review and approval of materials, and that -- that procedure does not allow use of materials that are not approved by a medical, regulatory and law review committee, so that process was in place with these revised materials.
Q. Where is that process written down?
A. We have a standard operating procedure that -- in place.
Q. Which standard operating procedure is that?
A. We have it. I don't have stickers.
MR. SNAPP: I have them. Do you

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want us to mark it?
MS. DICKINSON: I'm sorry. Sure.
MR. SNAPP: Would you like me to mark it.
MS. DICKINSON: Sure, sure.
MR. SNAPP: It will be Exhibit 47.
(Document marked for identification as Exhibit Purdue-Fanelli-47.)
BY MS. DICKINSON:
Q. And have you marked this as an exhibit, which exhibit?
A. Forty-seven.
Q. Forty-seven.
A. Sorry.
Q. Okay. What is Exhibit 47?
A. It's a standard operating procedure that describes -- did I call it an MR -- MRL, material review process. That process has been in place ever since I've been at Purdue and before, but it was put on paper, and this gives a good description of how that process occurs.

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Q. When was that process first put on paper?
A. I don't remember the date of the first one. It was in -- the process was in place, as I said, long before I got to Purdue, but I don't know the exact date.
Q. You may not know the exact date. Do you have a rough idea of when the process was put in place?
A. I know the process has always been in place.
Q. On paper?
A. Yeah, sorry.
I would think around 2002, in that -- in the early 2000s, I believe.
Q. Where would I go to find out?
A. We could look back at earlier versions of this document. This is version 3.
Q. Okay. Are there any response or any documents regarding the response to the warning letter in 2003 that we have not yet talked about?
A. Not that I'm aware of.
Q. Okay. Are there any other

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responses to the warning letter that are not summarized in these documents or that you haven't testified about? I'm trying to figure out if there's anything else I need to know that Purdue did in response to that warning letter.
A. I don't believe so. I mean, I don't think there's other documents.
Q. Okay. I think we're going to move on to topic 44 quickly. This may be a little bit of the same that we were just talking about.
Topic 44 asks for the process for determining the accuracy, completeness and legality of any sales, marketing, promotional, or educational information you made available to medical professionals, patients, or the public concerning any one or more opioid products in any format, including printed materials, videos, websites and in-person messaging or detailing by sales representatives.
Are you here prepared to testify on behalf of Purdue on that topic?
MR. SNAPP: I'll just state for the record that he's prepared to

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testify, as with all the topics in your deposition notice, with respect to OxyContin, Hysingla ER and Butrans. As we defined the topic, it's the process for determining the accuracy, completeness and legality of sales, marketing, promotional, or educational material -- I'm sorry -- educational information Purdue made available to medical professionals, patients, or the public concerning OxyContin, Hysingla ER and Butrans in any format.
And just so the record is clear, in our objections to your definition of opioids and opioid products I think it was, we did specifically say that our testimony was only going to pertain to Hysingla, OxyContin and Butrans.
BY MS. DICKINSON:
Q. Okay. So, Dr. Fanelli, again, you are not here prepared to testify on topic 44 as written; is that correct?
A. Yes.
Q. Okay. What was the process at

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Purdue starting in 1995 for determining the accuracy, completeness and legality of its sales, marketing and promotional materials, for OxyContin, let's start there?
A. Sure. As I mentioned, related to Exhibit 47 and to the previous question, we had review of material, always have had review of material -- we call it MRL, medical, regulatory and legal review, according to a process that each of those disciplines review and sign off on any materials. It's presented by -- the piece of material is -- and it's changed over time, now it's electronic, but, you know, the presentation by the material review is reviewed and approved by those three different disciplines.
Q. Is that process -- was that process written down anywhere in the time period 1995 to 2002?
A. I'm not aware if it was written down or not.
Q. So in preparing for your testimony today, did you ask anyone if that process had been written down in the period 1995

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to 2002?
A. I didn't ask if it was written down. I asked what the process was, or I didn't ask what the process was. I knew when I joined what the process was, and it had been going as long as I'm aware of.
Q. Okay. You joined the company in 2000?
A. Correct.
Q. Correct?
And your testimony is that there was no written policy at that time identifying the process for determining the accuracy, completeness and legality of sales and promotional materials; is that right?
A. Let me correct.
MR. SNAPP: Object to the form.
THE WITNESS: Sorry. I'm not aware if it was written down at that time.
BY MS. DICKINSON:
Q. And you didn't ask anyone if it was written down in preparation for this deposition, correct?

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MR. SNAPP: Object to the form.
THE WITNESS: Correct.
BY MS. DICKINSON:
Q. Did you talk to anyone in preparation for topic 44, other than your lawyers?
A. No.
Q. Did you review any documents in preparation for this topic, other than Exhibit 47?
A. No.
Q. Is Exhibit 47 the process that has been in place since -- for the entire time period 1990 to the present?
A. So --
MR. SNAPP: Just to make the record clear, the judge ruled that the relevant discovery period is '95 to the present, not 1990.
BY MS. DICKINSON:
Q. Okay. Can we -- I don't think it matters much.
Does Exhibit --
MR. SNAPP: Well, there's been

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several questions about 1990 to the present.
MS. DICKINSON: Well, it's what the notice said, but we won't waste time on it.
Is Exhibit 47 --
MR. SNAPP: Judge's order trumps the notice, with all due respect. Go ahead.
BY MS. DICKINSON:
Q. Is Exhibit 47, the -- this document.
A. Got it.
Q. -- the process that has been in place from 1995 to the present?
A. So this -- the main parts of this process, yes, that I described about the three reviews.
This goes into -- it's changed. You know, it used to be in paper, those kinds of things. So this goes into putting into the electronic system, you know, and those kinds of things.
So the -- the process of, you

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know, what documents go through approval, who the reviewers are and the fact that these things are reviewed periodically, if they're still in existence, those main components of it have been exist -- have been in existence.
Q. And when was the first time that those were in existence in written form?
MR. SNAPP: Object to the form.
THE WITNESS: Again, I don't know when the first time was.
BY MS. DICKINSON:
Q. So your basis for testifying about the process from 1995 up until this written document in 2016 is your personal knowledge of the process; is that right?
A. That's correct, yes. In 2000 when I joined, I was involved in the process as well. Sorry.
Q. What was the actual -- this addresses print.
What was the actual process for making sure the sales representatives accurately and completely stated -- or I'm sorry, let's just start over.

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This talks about in-person messaging or detailing the topic.
What was the process for making sure that statements made in in-person detailing by sales representatives was accurate, complete and legal?
MR. SNAPP: Object to the form, beyond the scope.
THE WITNESS: So the approval of the materials we've talked about require the sign-off by those three representatives.
Materials cannot be -- are not even actually distributed prior to that, but before there -- depends on the material, of course, if it's a package insert, it's not that complicated, but there is training of the sales force, and those materials are also reviewed by that same group. It's not a -- I think it says that in here. Anyway, so there's training of the sales force and review of compliance by the corporate compliance group we talked about before,

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so those are the two ways they would be monitored.
BY MS. DICKINSON:
Q. So because of the process you were describing is it fair to say that any sales, marketing, promotional or educational information that Purdue made available to the medical professionals, patients or the public were reviewed and signed off on by someone at Purdue?
A. Could you -- yes. You're say -- our communication and marketing materials are approved, yes.
Q. And that's true from 1995 to the present; is that right?
A. Yes.
Q. So someone approved the I got my life back video that was shown in 2001; is that right?
MR. SNAPP: Object to the form.
THE WITNESS: I'm not aware of that. Review materials that don't describe a product, there are -- there are exceptions. I think it says it in

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the SOP, and I'm not sure what the scope of those were. For instance, product labeling, I mentioned that about the package insert, given to consultants there were exceptions, but I'm not aware of that particular piece.
BY MS. DICKINSON:
Q. Did this process not apply to unbranded marketing materials that didn't mention a product specifically?
MR. SNAPP: Object to the form.
THE WITNESS: It does refer to nonbranded materials in its current form.
BY MS. DICKINSON:
Q. Okay. And the process applied to each and every marketing material at Purdue, right, the process you described and is in Exhibit 47; is that right?
A. As described in this, yes. Now -- yes.
Q. So a video distributed to 20,000 doctors went through this process?
MR. SNAPP: Object to the form.

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THE WITNESS: Yeah.
BY MS. DICKINSON:
Q. Yes? Fair?
A. I can't be sure that it did.
Q. What happens if it didn't?
MR. SNAPP: Object to the form.
THE WITNESS: So policies and procedures, as mentioned in FDA's warning letter, changed over time, as feedback from FDA is received and gained an understanding of the rules and regulations around -- around promotion, and Purdue's policies have also changed over time.
BY MS. DICKINSON:
Q. What policies are you talking about?
A. The review of these materials that you're talking about, the extent, whether or not a price list is reviewed or a particular video, those kinds of policies.
Q. Was there a period of time where certain marketing materials did not get reviewed in this process we were talking about?

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A. They would be assessed, but I don't know -- I'm not aware that there were times where they weren't reviewed.
Q. I guess I'm confused.
A. All branded material were always reviewed. I'm not sure about nonbranded materials, you know, how they fit into this process.
Q. And when you say brand --
A. In the early -- yeah.
Q. When you say "branded materials," that's something mentioning the product by name, correct?
A. Correct.
Q. And so anything mentioning the product by name, at all times from 1995 to present were reviewed by the company; is that right? Is that right?
MR. SNAPP: Object to the form.
THE WITNESS: I believe so.
BY MS. DICKINSON:
Q. And you're not certain if the unbranded materials were subject to that same scrutiny; is that right?

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A. The only thing I'm correct about the unbranded. In terms of the branded, the period of '95 to 2000, I'm not -- I don't have the -- I'm not that familiar with that, the details of that procedure.
Q. And you didn't familiarize yourself with the details of that procedure to answer this question today on behalf of Purdue; is that right?
MR. SNAPP: Object to the form.
THE WITNESS: That's right.
MS. DICKINSON: Take five minutes. I might be wrapping up.
THE VIDEOGRAPHER: The time is 2:57 p.m., going off the record. Remove your microphone.
(Brief recess.)
THE VIDEOGRAPHER: We are back on the record. The time is 3:13 p.m.
MS. DICKINSON: Dr. Fanelli, we're back on the record. I have finished the questions I have on those topics for you today. We have agreed to do topic 29 tomorrow.

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So for now I'm going to turn it over to some of the other counsel who I know are going to ask questions, and that's all I have for now. I appreciate your time.
THE WITNESS: Okay, you're welcome.
THE VIDEOGRAPHER: Go off the record.
MS. DICKINSON: You want to just go off for a second.
THE VIDEOGRAPHER: I can tell you how much. So we used up four hours and 39 minutes. Should I go off the record?
MR. STEWART: Yeah.
THE VIDEOGRAPHER: The time is 3:14 p.m., off the record.
(Documents marked for identification as Exhibit Purdue-Fanelli-48, 49, 50, 51 and 52.)
THE VIDEOGRAPHER: All right. We are back on the record. The time is 3:36 p.m.
BY MR. STEWART:

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Q. Dr. Fanelli, I represent the Tennessee plaintiffs in separate litigation. Obviously, I know that there's certain rules with respect to timing of 30(b)(6) depositions in the federal cases. We're under Tennessee rule 30.02(6) that does not have any timing requirements, and none of that applies to our cases. I'm planning to keep my questioning to two hours, as I notified opposing counsel.
Also, discovery, at least with respect to the Tennessee litigation, is in its infancy. Obviously, we're going to probably take our own 30.02(6) corporation deposition in the Tennessee cases, notwithstanding our presence here today.
Do you recall, Dr. Fanelli, talking about the material approval process?
A. Yes.
Q. And that's the process whereby Purdue would analyze materials that it was putting out into the public or to medical providers talking about OxyContin and other drugs?
A. Correct.

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Q. And I believe you testified that it applied to nonbranded materials?
A. Yes.
Q. When you say "nonbranded materials," did that include materials that third parties in which Purdue was a member or a funder produced?
MR. SNAPP: Object to the form.
THE WITNESS: Yeah, could you repeat the question so --
BY MR. STEWART:
Q. Yeah, I'm just asking when you had an organization that Purdue is a part of or a funder of and it was putting out materials about pain management about drugs that Purdue produced, would Purdue apply its material approval process to those materials?
A. So this is -- could you give me -- so --
Q. I'll give you a couple examples. Maybe you can just tell me.
A. That's good.
Q. You've got in front of you Exhibit 48. I think it's called "Partners

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Against Pain"?
A. Sorry, yeah.
Q. Why don't you just confirm for the record, is that the right exhibit number?
A. Yes, 48 it says visit our website.
Q. That's Partners Against Pain?
A. Correct.
Q. Do you see that?
A. Yes.
Q. Okay. Can you look at that and tell me whether this is the sort of information that would be subject to Purdue's material approval process that you've described in your testimony?
A. It is.
Q. And now can you look at another document, do you see Exhibit 49 is something called "A Policymaker's Guide to Understanding Pain & Its Management"?
A. Forty-nine?
Q. Perhaps.
A. Sorry.
Q. Do you have in front of you a

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policy --
A. I got it, yes, this document.
Q. Is it, in fact, Exhibit 49?
A. Yes, it is.
Q. Okay. And if you look at Exhibit 49, do you recognize that document?
A. No, I do not recognize it.
Q. Do you see that it's a document produced by the American Pain Foundation?
A. Yes.
Q. Is that an organization you're familiar with?
A. I know of it.
Q. What do you know about it?
A. All I -- you know, it's not part of my responsibility to deal with outside organizations, but I understand it to be a foundation, advocates for pain.
Q. Was it funded by Purdue, the American Pain Foundation?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: I do not know.
BY MR. STEWART:

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Q. Do you know whether American Pain Foundation -- strike that.
Do you know whether materials produced by the American Pain Foundation would be subject to Purdue's material approval process?
A. So production of this piece would not be part of Purdue's review process. It was produced by the American Pain Foundation, as far as I can tell.
Q. Do you know whether anybody in Purdue would typically review materials produced by the American Pain Foundation?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: I do not know that.
BY MR. STEWART:
Q. Sir, if you could turn to Exhibit 50, it's a document entitled "Treatment Options: A Guide for People Living with Pain."
Have you ever seen that document?
A. Not that I recall.
Q. Would this document be the sort of document that was reviewed according to

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Purdue's material approval process?
A. No, it would not be reviewed for creation of this document.
Q. Sounds like anything that the American Pain Foundation produced would not be subject to Purdue's material approval process, fair?
A. Correct.
Q. Just so the record is clear --
A. As I understand.
Q. Just so the record is clear, earlier in your testimony you agreed to a definition of Purdue that would encompass three different entities.
Do you recall doing that?
A. Yes.
Q. And we can still agree that that's what we're talking about when we say the word Purdue?
A. Yes.
Q. You've got another exhibit, it's Exhibit 51, and it is entitled "Complexities of Caring for People in Pain."
Can you look at that and see

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whether you're familiar with it?
A. I'm not familiar with it. Parts of it.
Q. What are you familiar with?
A. Actually, I don't recognize this piece itself.
Q. If it's a Purdue presentation that would have been given to physicians and other prescribers outside the company, would it have to go through the material approval process?
A. It says, yeah, produced by Purdue. Yes, it would have gone through that process.
Q. The point is if Purdue is speaking to prescribers through its own branded materials, whether it's a website, a PowerPoint presentation, approved statements by salespeople or a pamphlet, that all has to be approved through this approval process, the material approval process?
A. That's correct.
MR. SNAPP: Object to the form.
BY MR. STEWART:

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Q. I've got one final document in front of you, and it's Exhibit 52 entitled "Exit Wounds."
Do you see that?
A. Yes.
Q. Have you ever seen "Exit Wounds" before?
A. No, I have not.
Q. Can you look at it and tell me whether or not it is a document that would be subject to Purdue's material approval process?
A. I cannot -- I don't believe it was, but I don't see the date. September? I don't believe this was or would have been.
Q. As part of the material approval process, it's the standard that Purdue will not produce materials that contain statements that are not backed by medical science?
A. Could you repeat that. There were a couple negatives in there.
Q. The material approval process, is one goal of Purdue's material approval process to make sure that statements made about its products are consistent with existing medical

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science?
A. Yes, that's part of it.
Q. I take it as part of the material approval process, if something is stated in a document that is not backed by medical studies, then the statement is removed from the materials?
A. So we talked about the MRL, medical, regulatory and legal review.
Q. I'm talking about the material approval process, which I think you described as the MRL process.
A. Yes, yeah. So the medical information would be reviewed for support, you know, is there other publications, is it part of the information about the product and so forth.
Q. So, for example, if -- and if the US Food and Drug Administration told Purdue, this is the science, then you would want to adhere to the directives of the Food and Drug Administration, fair?
MR. SNAPP: Object to the form.
THE WITNESS: That's correct.
BY MR. STEWART:

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Q. I mean, you remember getting -- you discussed earlier in your testimony a warning letter that Purdue received with respect to some advertisements in the journal for the American Medical Association.

Do you remember that?

A. Yes.

Q. And do you remember that the warning letter -- in the warning letter the FDA was concerned and warned Purdue that it was failing to communicate -- to adequately communicate the abuse risks related to OxyContin?

MR. SNAPP: Object to the form.

THE WITNESS: I'd have to see -- which document were you referring to, the warning letter?

BY MR. STEWART:

Q. The warning letter. Go ahead, yeah.

A. What number do you have on there?

MR. SNAPP: What exhibit number is it?

MR. STEWART: I don't have the

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exhibit.

MS. DICKINSON: I think it was 39.

THE WITNESS: What's the date on that one? There were two versions, so on the front page. Is it December?

MR. SNAPP: Here's the January.

THE WITNESS: Is it the letter from --

BY MR. STEWART:

Q. I'm going to tell you, I don't see a date.

A. Who is it addressed to? Sorry.

Q. Michael Friedman.

A. Okay.

Q. Do you have a warning letter in front of you?

A. Yeah, I do.

Q. What exhibit do you have on it?

A. 41.

Q. And turn to page 2 of the warning letter. Do you see where the FDA says on the second sentence from the top, "The combination in these advertisements of suggesting such a

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broad use of this drug to treat pain without disclosing a potential for abuse with the drug and serious, potentially fatal risks associated with its use, is especially egregious and alarming in its potential impact on the public health."

Do you see that?

A. Yes.

Q. Now, once the FDA tells you that, at least at that point, doesn't Purdue have an obligation to make sure that it does not repeat the offending statements in future materials?

A. Yes. Purdue actually provided a response and removed all the materials.

Q. I guess my -- go ahead.

A. That the FDA agreed with, yeah.

Q. And my point is, though, it's not just the warning letter doesn't just warn you about a particular set of materials, it gives you -- it gives Purdue, the company, notice that there are certain statements that are not acceptable, and that notice applies to all future communications to providers, fair?

MR. SNAPP: Object to the form.

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THE WITNESS: It talks about -- yes, it's not just the materials that are mentioned.

BY MR. STEWART:

Q. I mean, you wouldn't then defy a warning letter from the FDA in a future set of materials?

MR. SNAPP: Object to the form.

THE WITNESS: We would follow the recommendations of the FDA as part of our procedure.

BY MR. STEWART:

Q. And that's not just to a warning letter, in general, when the FDA issues a statement about science say, with respect to OxyContin, then it's Purdue's duty to follow that recommendation, fair?

MR. SNAPP: Object to the form, scope.

THE WITNESS: We do have a -- we collect those actually and have a guide on how to address them in future communication.

BY MR. STEWART:

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Q. Because you want to make sure that your communications with providers fulfill Purdue's duty to not say things to providers that are inconsistent with the guidance from the FDA, fair?
A. That's correct.
Q. Tell me, what about the guilty plea that Purdue and its executives entered into in 2007, do you use the guilty plea as guidance when determining what to say in Purdue materials from 2007 forward?
MR. SNAPP: Object to the form.
THE WITNESS: We -- I'm not that aware of -- it's not part of my responsibility, the legal part of those, the pleas and so forth, but we take all messages that we have related to the agency's view on messaging when we review materials moving forward. Sorry.
BY MR. STEWART:
Q. I noticed earlier you said you'd never seen the guilty plea. Do you remember testifying to that?
A. Mm-hmm.

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Q. My question is how can you determine as part of the materials review process that Purdue is not making false statements if you don't know the false statements articulated in the guilty plea?
A. So we --
MR. SNAPP: Object to the form.
THE WITNESS: Sorry. As I mentioned, there is medical, regulatory and law are part of that review, and the law department is responsible for that aspect of a review.
BY MR. STEWART:
Q. So somewhere in the review process if -- and you're welcome to look at Exhibit 15, which is the Agreed Statement of Facts for the guilty plea, but, you know, the Agreed Statement of Facts states that beginning on or about December 12th, 1995, and continuing on for about June 30th, 2001, certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion and less likely to cause

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tolerance and withdrawal than other pain medications, and then it lists some examples.
Do you remember that?
A. What page are you on? Can I --
Q. I'm on page 5 and 6.
A. Yes.
Q. The point is from the point that Purdue pled guilty to misbranding, I take it that it assumed a duty not to repeat these false statements to providers, whether through pamphlets, websites, salespersons or other means?
MR. SNAPP: Object to the form, beyond the scope.
BY MR. STEWART:
Q. You can answer.
A. Yes, those while -- while -- again, I said that this is not, you know, a document that we reviewed or I personally reviewed. There were changes that were made based on that timing and those events on messaging going forward, yes.
Q. But the point is the system should ensure the system for -- strike that.

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The system Purdue has for reviewing materials before they're distributed to prescribers should weed out statements that repeat misstatements for which Purdue pled guilty in its guilty plea, fair?
MR. SNAPP: Object to the form.
THE WITNESS: I would say that's fair, yes.
(Document marked for identification as Exhibit Purdue-Fanelli-53.)
BY MR. STEWART:
Q. Dr. Fanelli, you have in front of you a document, can you tell me if it's marked with an exhibit sticker?
A. Exhibit 53.
Q. And do you recognize the exhibit?
A. Yes.
Q. What is it?
A. It's a submission to the FDA of a review publication.
Q. And --
A. I'm sorry. It was a reviewed document. I don't know if it was published.

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Q. Were you involved with the submission?
A. Yes, I was the one, as the regulatory liaison, who submitted it to FDA.
Q. And can you tell me briefly about your process for getting something like this approved before you submit it?
A. To submit to FDA?
Q. Sure. Before you got this document that's Exhibit 53 and submit it to the FDA, what sort of approvals did you get within the company?
A. So this is authored by -- I have to look and see -- what year is this? It's 2013. The contact for the content of the review -- it's a literature review is Dr. Craig Landau. I'm not sure of all of the individuals who were involved in putting the material together. The groups we talked about earlier today, R&D and medical would have been involved in producing it, and this is a general topic, so it would have been -- you know, it's outside of one individual product description, so it's not part of a project team. It would have been

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reviewed and the determination for submission would have been made by the groups of individuals involved in that.
Q. Would it be the sort of thing you'd review at regulatory affairs group staff meetings?
A. This -- this is more outside of that. It's more of a -- again, it's a review article, so within regulatory, again, it's not responding to an FDA request or a, you know, development, for instance, a labeling change or something like that. It was providing some research that was done, so it would have been discussed at regulatory affairs, but the decision would have been outside of that, among the authors and the executives on -- who were putting that together, and I was -- I would be part of that, of course.
Q. Would the CEO be involved in reviewing this document before it went out to the FDA?
A. Could have been. I'm not sure at this time.
It raises to the level of

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executive committee for sure.
Q. And executive committee is made up of?
A. Mostly the heads of the departments.
Q. Do you see the last sentence in the second paragraph in your routing letter to Dr. Rappaport, you say, "The results of this review indicated that for those patients who choose to continue to take opioids beyond 3 months, efficacy and safety are generally maintained through 52 weeks, and that beyond 52 weeks, limited data suggest a critical need for additional studies to determine the long-term safety and efficacy for durations of therapy beyond 1 year."
Do you see that?
A. I do.
Q. Okay. And is that a statement that reflects your understanding of science as of May 28th, 2013?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: Yes, it is.

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BY MR. STEWART:
Q. I take it, because you were involved with this, you have individual knowledge of this particular document, fair?
A. I was not an author, but I have some knowledge, yes.
Q. As of May 28th, 2013 was Purdue in a position using IMS data and other data to determine the number of patients in the United States that have been -- that were receiving prescriptions and had been doing so for over a year?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: I was going to -- not part of my responsibility.
BY MR. STEWART:
Q. Do you know the answer?
A. Could you ask the question again.
Q. Sure. You know, Purdue looks at IMS data for a variety of items of information about prescribing, fair?
A. Yes.
Q. Can Purdue determine how many

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people have been receiving a long-term opioid medication for over a year through that data?
MR. SNAPP: Object to the form. Objection as beyond the scope.
THE WITNESS: I'm not aware of the -- the IMS data, you know, what the details of -- can you follow -- can you get information on an individual patient across the year, for instance. I think that was what your question was.
MR. STEWART: And, counsel, I'll just say you're making scope objections, and I'll just ask you, I mean, I'm happy to continue this in his individual deposition, if that's what you're suggesting.
MR. SNAPP: I just -- I'm having a hard time understanding how IMS data is related to any of the topics that were noticed for this deposition, but if you can identify it --
MR. STEWART: I think it's related --
MR. SNAPP: -- I'll make my

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objections, you can ask your questions.
MR. STEWART: I'll tell you what, I think it's related to topics 7 and 10, and what I'll do is ask a certain number of questions, and then I'll continue the questioning tomorrow in your individual deposition.
BY MR. STEWART:
Q. Question, could you turn to page 6, which is marked with a Bates number 33091.
A. Okay.
Q. Do you see in the middle of the page, section 2 it states, "The relative risk of developing an addictive disorder in patients with chronic non-cancer pain who are treated with chronic opioid therapy remains unknown."
Do you see that?
A. Yes.
Q. Okay. So that's a conclusion or a statement that Purdue is making to the US Food and Drug Administration?
MR. SNAPP: Object to the form.
THE WITNESS: It's part of a report that was reviewing the literature

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and it is -- was submitted to the FDA.
BY MR. STEWART:
Q. And I take it one of the policies, or among the policies and procedures for interacting with the FDA, would be a policy of not submitting a report with a statement that Purdue didn't agree with?
MR. SNAPP: Object to the form.
THE WITNESS: That's correct.
BY MR. STEWART:
Q. I mean, this is a statement by Purdue to the US Food and Drug Administration, fair?
MR. SNAPP: Object to the form.
THE WITNESS: It's a submission of a literature review that was submitted to the FDA, yes.
BY MR. STEWART:
Q. So this is published in 2013.
If we were to look back prior to 2013 and see statements by Purdue or anyone else suggesting knowledge of how much addictive disorder would be associated with the prescribing of chronic opioid therapy, those

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statements wouldn't be consistent with science, fair?
MR. SNAPP: Object to the form, scope.
THE WITNESS: So this is talking about the relative risk. The science around monitoring addictive disorder in those patients has evolved over time. So statements when they are made are based on the science at that particular time, and at this time we're still -- we're still studying it now, we talked about the ten postmarketing commitment studies. Those are looking at the rates of addictive behavior today, and FDA and all the sponsors are continuing to revise the science around that, and this is -- was a statement at that particular time.
BY MR. STEWART:
Q. So here's my confusion: if something is scientifically unknown in 2013, can't we assume that it was scientifically unknown in, say, 1996?

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MR. SNAPP: Object to the form.
THE WITNESS: No, I wouldn't say that -- we learned -- just because, you know, a statement is made at one time and it's revised later doesn't mean that at that time someone wasn't making a scientific conclusion based on the information they had, it changes.
BY MR. STEWART:
Q. Tell me then, Dr. Fanelli, when specifically did this statement that you -- that "the relative risk of developing an addictive disorder in patients with chronic non-cancer pain who are treated with chronic opioid therapy remains unknown," when did that become a statement consistent with current medical science?
MR. SNAPP: Object to the form, beyond the scope.
THE WITNESS: I don't know. When this was written and I don't know -- it was submitted in 2013, that was a statement made following review of the literature at that time.

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BY MR. STEWART:
Q. Well, tell me any literature that you are aware of, okay, that justified a different conclusion with respect to chronic opioid therapy and the risks of addiction?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: So I'm not a scientist in that area, the head of regulatory affairs, and I don't have an answer for that.
BY MR. STEWART:
Q. Okay. Would your policies and procedures at Purdue for interacting with the FDA include a policy for making sure that a statement like this wasn't inconsistent with some other study?
A. The review of a document such as this, a publication, although I don't think this was published. I can't say that or a summary document is reviewed by -- it's outside of a material review because this is not -- it's not for publication or it's not for presentation, it's for submission to FDA. So that would be

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reviewed by a different group of individuals, but it would be reviewed for accuracy, for sure.
Q. Who in Purdue could tell me or put it this way: who would have reviewed this document who could tell me whether Purdue ever had justification for a different position, other than the one that we're talking about with respect to the risk of addiction?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: We have a -- in our medical affairs department, we have a group of epidemiological scientists, and that's part of their responsibility.
BY MR. STEWART:
Q. Who -- if the FDA called Purdue today and said, you know, we see that you have said in 2013 that you can't predict the likelihood of addiction in connection with chronic opioid therapy, we'd like to know whether you've taken a different position in the past and what the basis was, who would they talk to?
MR. SNAPP: Object to the form.

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THE WITNESS: It depend -- you know, FDA would -- in order to answer that I'd need much more specific statements about what the material was, you know, how it was submitted and so forth.
BY MR. STEWART:
Q. Who in Purdue could detail Purdue's evolving position over time, if it did evolve, with respect to the risk of addiction related to chronic opioid therapy?
MR. SNAPP: Object to the form, beyond the scope.
THE WITNESS: Today that would be our medical affairs or our -- and the risk -- there's a group, the epidemiologists I mentioned within Purdue.
BY MR. STEWART:
Q. And who's that?
A. It's changed very recently. It's under Marcelo Bigal, who is our chief medical officer.
Q. And so OxyContin is one drug used

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to provide chronic opioid therapy, fair?
A. Yes.
Q. And OxyContin has been marketed by Purdue for over 20 years since 1996?
A. Correct.
Q. And what you're admitting in this document that's before you is that Purdue doesn't believe that it knows or has science to support a rate of addiction stemming from chronic opioid therapy with OxyContin, fair?
MR. SNAPP: Object to the form, beyond the scope.
THE WITNESS: Could you repeat the --
BY MR. STEWART:
Q. Sure.
Is it -- when a jury or a judge is looking at this document, I take it they could conclude that Purdue has been marketing a drug, OxyContin for chronic opioid therapy for 22 years and now admits that it has no idea what the risk of developing addictive disorder from that drug is, fair?
MR. SNAPP: Object to the form,

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beyond the scope.
THE WITNESS: It says the relative risk, so that's what it's talking about, relative risk, not no idea.
BY MR. STEWART:
Q. Okay. It doesn't know -- Purdue is admitting here that 22 years into its marketing of OxyContin for chronic opioid therapy, it doesn't know the relative risk that that therapy poses for developing an addictive disorder?
MR. SNAPP: Object to the form, beyond the scope.
THE WITNESS: That's correct.
BY MR. STEWART:
Q. Turn back to the first page, your routing letter in Exhibit 53.
A. Mm-hmm.
Q. Do you see that you state in the second to last sentence in the second paragraph, based upon -- a quote -- strike that. Let's make this clearer.
Do you see you state in your

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routing letter, "Based upon the literature reviewed, it is estimated that the prevalence of aberrant drug behaviors and abuse of opioids ranges from 0.08 to 32%, and the prevalence of opioid use disorder ranges from 2.7 to 25.8% in patients with CNCP treated with chronic opioid therapy."
Do you see that?
A. Yes.
Q. That statement reflects the company's understanding of the current science?
A. No. What it reflects is the literature that was reviewed, and there's a table here with all those publications and the list, and if you review those publications, in that review, it's talking about they state the prevalence as you just described it.
Q. So I take it your -- Purdue's policies and procedures for interacting with the FDA are such that you wouldn't include in your analysis studies that you thought were without any scientific basis?
MR. SNAPP: Object to the form.
THE WITNESS: That's correct, and

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what this review is, looking at that publication, providing it to FDA so they're aware of what science is out there at the current time about that.
BY MR. STEWART:
Q. And some of the studies that Purdue is bringing -- or is citing to the FDA find that between a quarter and a third of the people that have chronic opioid therapy develop abuse of opioids or opioid use disorder, fair?
MR. SNAPP: Object to the form.
THE WITNESS: Can you point out where you --
BY MR. STEWART:
Q. Well, I'm just saying --
A. Oh, I see.
Q. -- your conclusion is that there are studies that you cite that suggest that 32% of people involved in chronic -- in chronic opioid therapy show aberrant drug behaviors and abuse of opioids, fair?
A. What it says is the prevalence of aberrant drug behaviors in these articles range from 0.08 to 32%.

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Q. And then the prevalence of opioid abuse disorder ranges from 2.7 to 25.8%?
A. That's correct.
Q. And does -- has Purdue ever evaluated the studies that show that nearly a third of people that receive treatment -- that receive chronic opioid therapy show behaviors, aberrant drug behaviors and abuse of opioids?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: What this literature review shows is that the -- and I mentioned this before, the science around prevalence of aberrant drug behaviors, the science around opioid use disorder is an evolving science. It's relatively new, and that's why there's such a wide variety. 0.08 to 32%, 3% to 26%, 25.8.
And the point of that is to say -- and the next sentence says it, "these studies do not permit estimates of incidence for either aberrant drug behaviors or opioid use disorder since

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typically the history" -- anyway, there's other issues related to the patient studies. There's not adequate history, and that's why I mentioned about the science continuing to evolve and we're continuing to study this.
BY MR. STEWART:
Q. Turn to page 36, sir.
A. The Bates or --
Q. Turn to page -- not the Bates, 36 of Exhibit 53.
A. Okay.
Q. And do you see that the Bates number on that page ends in the number 3121?
A. Yes.
Q. Okay. Do you see three sentences down in section 5.1.1, the report states "all 20 studies described opioid abuse or aberrant behaviors"?
A. Starts with while?
Q. Yes. You see that?
A. I see that, yeah.
Q. Okay. Every study that is reviewed described that in patients that were on

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long-term opioid therapy, fair?
MR. SNAPP: Object to the form.
THE WITNESS: It says -- it describes opiate abuse, but I'd have to look at them to -- but that appears to be what it says.
BY MR. STEWART:
Q. I take it -- I mean, this study right here, you've submitted it to the FDA, given the policies and procedures of Purdue, a Court can look at this document and see that this is a statement that Purdue is making to a federal body, trying to give its view about the current state of the science in this area, fair?
MR. SNAPP: Object to the form.
THE WITNESS: Yes, that's fair.
BY MR. STEWART:
Q. Do you see you've got three studies that you -- that you highlight, an Adams study, Naliboff study and a Reid study? That's on pages 36 and 37.
A. Study one, Adams. Study two, I don't know how to say it, but, yes, I see those three.

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Q. Are you familiar with those studies?
A. No, not in --
Q. We'd have to read the report to determine --
A. Yes.
Q. -- how the company position on those studies?
A. Yes.
(Document marked for identification as Exhibit Purdue-Fanelli-54.)
MR. SNAPP: Dr. Fanelli was just saying we might need to take a break in about 20 minutes [redacted]
MR. STEWART: That's fine. We can take it now, if you'd like.
THE WITNESS: No, 20 minutes will be good.
MR. STEWART: Perfect.
BY MR. STEWART:
Q. Dr. Fanelli, you have a document in front of you, it's Exhibit 54?

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A. Yes.
Q. And have you recognize -- do you recognize it?
A. No, I do not.
Q. Okay. It's not something you were involved with?
A. Well, it's an appendix. I don't know what was in front of this.
Q. Okay.
(Document marked for identification as Exhibit Purdue-Fanelli-55.)
BY MR. STEWART:
Q. I've given you an Exhibit 55 that I believe is a routing letter of the appendix. Can you look at it and tell me whether I'm correct?
A. So this -- this cover letter from October 25th, 2013 mentions, if you look at the second paragraph, that we're providing FDA with a courtesy copy of a submission to the FDA -- the docket containing a Citizen Petition with exhibits. So this is Appendix C.
I'm not sure if this is all that

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went with this letter.
Q. Let me ask you, could you turn -- go to Exhibit 54.
A. Uh-huh.
Q. Which is the larger exhibit, the appendix, and turn to the Bates stamp page that ends in 8177. It's about 100 pages in.
A. I'm there.
Q. Okay. Do you recognize that PowerPoint?
A. No, I do not.
Q. So you have not -- you're not familiar with the study described in the PowerPoint?
A. I know about it, but -- and I have seen this, but it's been a while.
Q. Okay. So you have seen this PowerPoint?
A. Let me -- can I look through the whole thing?
Q. Yes, absolutely.
A. (Witness reviews document.)
Yes.
Q. And what does it -- what does it

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involve? What does the PowerPoint tell the FDA?
A. Well, so, again, this is -- without seeing the whole -- the other appendices and all, it's part of showing FDA or providing to FDA for their information part of a Citizen's Petition about changes in prescriptions after the introduction of the reformulation of OxyContin.
Q. And do you remember the study being conducted that's described in this PowerPoint presentation?
A. I do not.
Q. Do you remember that Purdue compared physicians that were in its Region 0 program which its salespeople did not visit against other -- other physicians that were not in the Region 0 program?
A. Yes, I know that we did that.
Q. Okay.
A. And it looks like that's part of this.
Q. What do you know about that study?
MR. SNAPP: Objection, beyond the

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scope.
THE WITNESS: I don't recall the findings or, you know, actually the actual conduct.
BY MR. STEWART:
Q. Let me ask you this: If this PowerPoint was submitted to the FDA, I take it, based on Purdue's procedures, it would contain an accurate description of the study?
A. That's correct.
Q. You know, someone could look at the PowerPoint and understand that this was information that was designed to convey to the FDA what Purdue had found with respect to this study of comparative prescribing practices by different groups of doctors?
MR. SNAPP: Object to the form.
BY MR. STEWART:
Q. Fair?
A. I'd have to read the study to understand, but what -- again, it's looking at changes in prescriptions from the title, but I'd have to read the study, not only the presentation, which is a summary of that, but,

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again, it's part of a Citizen's Petition, and I'd have to look back at the -- I'm not sure what docket it was. So, yes, it's related to, as it says in the letter, that it was abuse deterrent science meeting by FDA, and it was providing information, I assume, that was relevant to that to the FDA.

Q. At the time that this was submitted, what was your role with respect to dealings with the FDA?

A. What day was that? Sorry.

Q. It looks like it was October 2013?

A. So I became head of regulatory affairs the next year. At this time, 2013, right before this, there were three different groups in regulatory, and I was head of one of those groups, which was all the FDA liaisons reported in to me and the project manager. So a regulatory person who was on a development project would report in to me.

Q. Would somebody that reported to you have been involved with this study, where doctors were compared with regard to their

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prescribing of OxyContin?

A. What do you mean by "involved with this study"?

Q. Well, I'm just trying to figure out you sound -- you know, I've handed you the PowerPoint that's part of Exhibit 54, and I'm just trying to figure out if it fell within your -- your responsibilities?

A. So Beth Conley is -- reported to me at the time. This is -- we filed to FD -- we forward to FDA responses to things like Citizens Petitions, to the FDA docket so they have the information that Purdue has relative, so the responsibility -- regulatory's responsibility is to understand, you know, what the document is, where it fits in correspondence with FDA and to provide that to the FDA.

Q. So it did fall within your responsibility?

A. Getting this to FDA did.

Q. Okay.

A. Conduct of the study and the details of the study are outside of regulatory.

Q. Who's responsible for what you

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call the contents of the study?

A. That particular study is the same group we were talking about before. Two former employees are listed on there from that group. I don't have -- what page was that? Here it is. Actually, three. Howard Chilcoat. I don't know Sayee, I think he's a statistician, and Paul and Robin Abrams is also listed on there, who is an attorney. She was the lead -- part of the SOPs we talked about earlier today, the ADD, which is mentioned in this publication falls under the law department, so that's why those would be the responsible individuals.

Q. You've got a document in front of you marked Exhibit 56. It's a thick one. Do you see it? It's coming.

(Document marked for identification as Exhibit Purdue-Fanelli-56.)

THE WITNESS: I put these out of order sorry. Should I keep this one?

MR. STEWART: No. Move on to the next.

THE WITNESS: Okay.

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BY MR. STEWART:

Q. Do you recognize Exhibit 56?

A. From the title, but it doesn't have the covering information, so I recognize it as a response to FDA -- an information request, call it an IR from FDA, so final IR questions.

Q. And you're familiar with the policies and procedures that Purdue would have for responding to an information request from the FDA?

A. Yes.

Q. Can you generally tell me what Purdue's obligation is when you get an FDA information request?

A. So information requests come from FDA mostly related to applications under review or supplements under review or package insert supplements and so forth. They come in the form, either e-mail or a written form, and, generally, in FDA's -- obviously they're not all the same, depends on what the FDA is asking about.

FDA provides comments, requests related to some material and provides -- usually

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FDA actually usually provides what their request is in terms of timing of response and so forth, so that's an information request.

Q. When a comp -- when Purdue responds to an FDA information request, I take it its responses are intended to reflect its understanding of the truth?

A. Yes.

Q. This is meant to be a reliable document?

A. Mm-hmm, yes.

Q. You have procedures in place -- I mean, you have procedures in place to ensure that the FDA can read this document that's Exhibit 56 and understand what Purdue's position is with respect to its questions, fair?

A. That's our intent.

Q. Okay. Can you turn to -- can you turn to page Bates number 3819. You see there's a lengthy -- there's a question from the FDA about the RADARS Drug Diversion Study?

A. Yes, I see that.

Q. Do you know what that is? Do you know what the RADARS Drug Diversion Study is?

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A. I know what RADARS is. This particular study -- RADARS is involved -- it's actually a collection of detection sources to detect abuse, overdose and death, misuse, that was actually created at Purdue, but now it resides in Colorado. We have many studies, including in the class postmarket realm, I'm not sure, in each different products to use data from RADARS to answer questions around drug diversion and so forth. So but this particular study I'd have to -- I don't see a title. I'd have to go by what it says here.

Q. Let me ask you, you say that Purdue relies on RADARS to inform it about diversion with respect to a number of its products?

A. So RADARS is only one part that we talked about this earlier today. That's why there are 11 studies, ten of which are epidemiological like this is getting data from different sources. RADARS is one of those sources. Each of those individual sources, databases, if we're using Kaiser Permanente's database on patient use and so forth, each has

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their limitations based on where the data come from and so forth. RADARS, in fact, recently FDA uses RADARS as well to get data, and recently FDA identified an issue with one of the sources and informed both RADARS and all the sponsors that that data was going to be redone. So anyway, sorry to go on for so long, but that's what RADARS is all about.

So, yes, we rely on their data, data from every -- different sources have advantages and limitations, and I'll just stop there. Is that helpful? Did it answer your question?

Q. Yeah, I think it does.

In this -- in this particular response to the FDA, Purdue says, and it's the fifth paragraph down, "Previous results indicate that drug diversion data relate to real world events. Besides the apparent reduction in drug diversion, the introduction of reformulated OxyContin had similar decreases in the RADARS Poison Control Center Program, Opioid Treatment Program, Survey of Key Informants' Patients and StreetRx."

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Do you see that?

A. Yes.

Q. Okay. First of all, it sounds like you agree that drug diversion data from RADARS does relate to real world events; it shows what's going on on the street, fair?

MR. SNAPP: Object to the form and beyond the scope.

THE WITNESS: It's part of the picture, it provides data, yes.

BY MR. STEWART:

Q. I mean, Purdue uses it to figure out -- to measure diversion?

A. As I say, it's part of -- it's one of the things we look at. There are many different databases that we're currently trying to look at. We still have four -- after years working with FDA, we're actually in the final stages of finishing our postmarketing required studies for OxyContin. After working with FDA the last revision on their protocol that they asked us to revise was within the last year, but we're near -- two of those four studies have been submitted to the FDA, and there are two

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more still ongoing.
Q. And I think --
A. So all I'm saying is that the data are coming in now.
Q. All right. So you're saying it's one of the -- one of the datasets that Purdue uses to measure diversion?
A. Correct.
Q. And do you see in the last paragraph the document says, "Given that trends over time in drug diversion data are similar to trends from the Poison Control Center Program (in abuse and misuse), as well as admission rates to opioid treatment centers (addiction) and can detect changes at both product and geographically specific levels in response to interventions, drug diversion data should be considered relevant information for the postmarketing outcome described the FDA Guidance for Industry."
Do you see that?
A. Yes.
Q. And what Purdue is saying here is to the FDA, there's a reason that you can use

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this drug diversion data to measure diversion both at the product level and at the geographically specific level, fair?
MR. SNAPP: Object to the form, beyond the scope.
THE WITNESS: Could you repeat your question.
BY MR. STEWART:
Q. Sure.
What Purdue is telling the FDA here is you can use this drug diversion data from RADARS to measure diversion both at the product and the geographically specific level, fair?
MR. SNAPP: Object to the form and beyond the scope.
THE WITNESS: That's what it says there.
BY MR. STEWART:
Q. Yeah, it says, look, you can -- you can isolate diversion of a particular product like Oxycontin with this RADARS data?
MR. SNAPP: Same objections.
THE WITNESS: So, as I say,

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all -- now, I still don't have -- I don't have the cover letter, so I'm not exactly sure. It doesn't have a date on it either, although what it's referring to, FDA is -- if you go to the top of the next page, this is related to FDA's guidance to industry for the evaluation and labeling of abuse of current opioids.
FDA, I think this is related to -- and the Citizens Petition is related to providing FDA with points to consider as part of that guidance, although I'm not sure, since I don't have the cover letter.
And what that statement is saying is that those drug diversion data can detect changes in response to intervention and it does mention geographically.
BY MR. STEWART:
Q. And you just mentioned that there a -- there are a number of different systems that Purdue uses to measure diversion, fair?

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MR. SNAPP: Object to the form, beyond the scope.
THE WITNESS: There are studies ongoing to assess that.
BY MR. STEWART:
Q. And can you just tell me for each -- tell me just -- and I realize you answered this question earlier, but just to be clear, what tools like RADARS would Purdue use currently to measure the illegal drug market for diverted drugs in a particular area?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: Yeah, I'm not aware of the specific tools to address that.
BY MR. STEWART:
Q. Well, what -- I'm trying to draw off of what you said earlier.
You said Purdue uses a number of systems to evaluate diversion, so what systems would Purdue currently use to evaluate diversion in a given area?
MR. SNAPP: Objection, beyond the scope.

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THE WITNESS: So we have -- the postmarketing studies that we're doing and the industry is doing include, as I said, up to ten studies. They measure things such as doctor shopping, for example. They measure things such as -- and actually, you know, again, I'm not the scientists, the epidemiologists there, but it's just from my experience of interacting with FDA where my knowledge comes from, looking at databases from managed care organizations, for instance, on adverse events that are reported. So all those -- all those information are available and tools that are used to assess.

BY MR. STEWART:

Q. Do you recall Purdue undergoing an effort to measure whether or not the market for diverted drugs declined after it introduced reformulated OxyContin?

MR. SNAPP: Object to the form, objection, beyond the scope.

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THE WITNESS: We are -- those are -- that is exactly what the postmarketing studies continue to do. We've been doing that since -- for years, and we continue to study that.

BY MR. STEWART:

Q. And you, you're familiar with the postmarketing study process, fair, in your current --

A. Process, yes.

Q. If I wanted to talk to you, if I wanted to get a document for you that would allow you to provide as much knowledge as you have about measurement of diversion with respect to your postmarketing efforts, what document would I be looking for?

MR. SNAPP: Object to the form.

THE WITNESS: So my -- again is related to the process of how we deal with FDA, how we submit the protocols, how we get feedback from FDA on most protocols, how we submit the results, the timing. Each postmarketing requirement has a state of what the

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objectives are, we submit those in the protocol. So my role and responsibility is providing those to the scientists who then conduct the studies and then interact with FDA. All these studies are done with contracting to organizations such as RADARS, institutions such as Columbia University, they have a group there that's studying questionnaires, and we're designing them right now to assess opiate -- risk of opiate abuse and so forth. So that's the kind of responsibility that's mine.

MR. STEWART: Why don't we take a break.

THE WITNESS: Thanks.

THE VIDEOGRAPHER: Remove your microphones. The time is 4:41 p.m., off the record.

(Brief recess.)

THE VIDEOGRAPHER: We are back on the record, the time is 4:54.

BY MR. STEWART:

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Q. Sir, in reviewing materials for -- that are sent to federal regulators, you talked at times there's senior members of Purdue management that are involved, fair?

A. Sometimes, yes.

Q. What are those times, how would you define them?

A. Depends on what you mean.

Q. Yeah, when is it that, say, the board of Purdue gets involved with submission of things to federal regulator?

A. The board, when I say senior management, I'm speaking of up to the CEO, the board would rarely -- I can't think of an incident -- get involved in a submission to the FDA.

Q. So the highest level people would be the CEO and other top executives, fair?

A. Yes.

Q. Okay. You've got in front of you or you will an exhibit.

MR. STEWART: What number are we on? 57.

(Document marked for

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identification as Exhibit Purdue-Fanelli-57.)

BY MR. STEWART:

Q. Do you see it is an e-mail?

A. Hold on.

Q. It's a series of --

A. Oh, I gave away the --

Q. Okay. Do you see it's a series of e-mails?

A. That's what it appears to be, yes.

Q. And who's sending the e-mails? I think you've already talked about.

A. So it start -- are you on 154?

Q. Right. Why don't you -- do you see you have a series of e-mails in your hand?

A. Yes.

Q. They're a single exhibit?

A. Yeah.

Q. And the exhibit is 57; is that correct?

A. Yes.

Q. Okay. Let's just go through the e-mails front to back, fair?

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A. Okay.

Q. Do you see you have an e-mail in front of you that has the Bates Number 9154?

A. Yes.

Q. Okay. Do you see that -- and you're the third line from the bottom that you received the e-mail?

A. Yes.

Q. Okay. And do you see that the e-mail is entitled "RA Staff Meeting"?

A. Yes.

Q. Okay. What's that?

A. This one says International RA Staff Meeting.

At the time and the individual is the administrative assistant to Ron Hargreaves, who is the first individual on this -- what year was this? Sorry. This was sent -- do you know what I see is this is a recurring notice of a meeting that occurs every month, so I'm not -- well, it says 2002 to 2003.

Q. I'm just wondering, do you remember having meetings of that sort?

A. Yeah, we would -- this one is the

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international -- this particular e-mail goes to the international regulatory affairs staff. I was not a member of the international regulatory affairs staff.

Oh, I know what this is now. Sorry. I had to look at the entire -- so that's for the entire regulatory department.

At that time, you know, we had an international department and a US department. I was always when I came a member of the US regulatory affairs, but this looks like it's a joint meeting of all, if I look at the individuals.

Q. And if you're getting an invite to a meeting, are you going to attend, or how does that work?

A. It depends. I have three meetings today that I could not attend, so I usually would assign it to someone who works for me or have it covered by one of my associates.

Q. If you receive a meeting invite like this in Purdue, does that mean that someone is supposed to attend on your behalf?

A. It really depends on the agenda

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item. So if -- and also my role at the current time. You know, it would really depend. So there may -- let me further, you know, given the list of attendees, there could be someone who has a similar responsibility that I do who could cover for me, and I wouldn't -- they were already there, I wouldn't have to assign it.

Q. Now, you look five down from the top -- well, first of all, do you remember actually attending any of these meetings of this group?

MR. SNAPP: Objection, beyond the scope.

THE WITNESS: Yes, I can -- I can remember.

BY MR. STEWART:

Q. What was the purpose of that group, the international regulatory affairs group?

MR. SNAPP: Objection, beyond the scope.

THE WITNESS: So our -- it's a department meeting where we would discuss topics of interest to the entire

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department, generally.
BY MR. STEWART:
Q. So you talk about reports, for example, with respect to regulatory affairs?
MR. SNAPP: Object to the form.
THE WITNESS: We would generally talk about different projects, according to drug development products, marketed products and so forth. It could come up that a submission would be discussed, but it depends on the agenda and the day.
BY MR. STEWART:
Q. I noticed that five or four lines down in this list of folks that are notified, do you see there's a doctor, I think, Kathe Sackler?
A. Yes.
Q. Is that how you pronounce that Kathe?
A. Yes.
Q. Who is Kathe Sackler?
MR. SNAPP: Objection, beyond the scope.

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THE WITNESS: Member of the Board of Directors.
BY MR. STEWART:
Q. Okay. And is she also an officer in the company?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: I'm not sure how that's defined.
BY MS. DICKINSON:
Q. Well, does she have a title in the company in an active role?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: She's a member of the Board of Directors.
BY MR. STEWART:
Q. But outside of being a member of the board, does she have an active role --
A. Sort of like --
Q. -- in the operations of the company?
MR. SNAPP: Objection, beyond the scope.

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THE WITNESS: Not that I'm aware of.
BY MR. STEWART:
Q. Do you know if she has an office at Purdue?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: I believe she does.
BY MR. STEWART:
Q. Why would she be invited to a meeting of this sort? Is that pretty typical?
MR. SNAPP: Object to the form, beyond the scope.
THE WITNESS: Not that I'm aware of. I don't know.
BY MR. STEWART:
Q. Okay. What about Dr. Richard Sackler, who's that?
MR. SNAPP: Objection.
BY MR. STEWART:
Q. He's the next person on the list.
MR. SNAPP: Beyond the scope.
THE WITNESS: Another member of the Board of Directors.

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BY MR. STEWART:
Q. Did he also have a role as an officer of the company?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: He is a member of the board.
BY MR. STEWART:
Q. Has he ever had a role as president or CEO or anything else?
A. Oh, yes.
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: He was -- sorry, I apologize. You want to repeat it.
BY MR. STEWART:
Q. Yeah, go ahead. Richard Sackler, what sort of roles has he played, other than just being a member of the board?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: He was the -- I'm not sure of the exact title back then, president, CEO, head of the --

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BY MR. STEWART:
Q. He was the top executive of the company at this time, fair?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: Correct.
BY MR. STEWART:
Q. And do you remember a --
A. Can I -- I'm not exactly sure on this particular date, you know, when that changed.
Q. At some point he was the top executive in the company, correct?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: Correct.
BY MR. STEWART:
Q. Now, so do you remember attending a meeting with Kathe and Richard Sackler?
MR. SNAPP: Objection to the form.
BY MR. STEWART:
Q. Do you remember attending this particular meeting?

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A. No, do not.
Q. Have you attended meetings with Kathe Sackler?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: I have attended board meetings, no -- besides -- the only meetings that I had that included Dr. Richard and Dr. Kathe Sackler were board meetings, where I was as the head of regulatory or even before then as the head of a particular project reporting to the board on development programs and items such as that.
BY MR. STEWART:
Q. How many times have you had a meeting with -- have you attended a Purdue board meeting?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: I -- it would have to be a very rough estimate, a handful, I'd say. I worked at Purdue 18 years, maybe a dozen of those times. Usually

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those meetings are attended by the head of R&D, who I report to, and, again, I've only been the head of regulatory since 2014 so, you know...
BY MR. STEWART:
Q. Have most of your meetings with the board been since 2014 when you became head of regulatory?
A. No, they've been across the time. So when I first joined Purdue, I was on a couple of -- as the regulatory representative on a particular project. When that project came up for review, I might have gone to the board.
A good example of that is Butrans or buprenorphine transdermal system, I was the lead as if you look at the approval letter, I'm the person who signed those letters and submitted those, and discussions of the plans for those studies took place -- this is just an example, took place at a board meeting.
Q. Typically, when there's a meeting at Purdue, is there a calendar entry sent around like this?
A. Calendar invite is how folks find

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out about meetings.
Q. So if we wanted to know all the meetings that you've been invited to since 2002, the best way to do it would be to look at your calendar entries, fair?
MR. SNAPP: Object to the form. Objection, beyond the scope.
THE WITNESS: You could do that. It's not 100% accurate in terms of -- you know, it could be on my calendar, I might not have attended and so forth. It will definitely give you an idea of my day.
BY MR. STEWART:
Q. And that would be true for anybody on this e-mail right here, anybody that's been invited, fair?
MR. SNAPP: Object to the form.
THE WITNESS: So there are -- and this e-mail, again, is old, and I'm not sure, it doesn't look familiar to me either in terms of the formatting. Usually it has the name, but maybe that's how they were in 2002.

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There are folks that are included on invitations so they know they're occurring but not expected to be there so...

BY MR. STEWART:

Q. The point is it shows you who's invited to a meeting, not necessarily who attends is what you're saying?

A. It -- what it's indicating is who's -- who's been informed about the meeting. I'm not sure if they were all invited.

So, for instance, when I first saw this and thought it was an international regulatory, as I say, at different times there was a international separate group that had their own meetings, they would have let me know about it in case, you know, I had part of the agenda. And as you notice, this is -- at least it says here occurs every first Tuesday of every month, so this is a repeat meeting, so it goes on your calendar every month, and not all these people, you know, might have been invited each month. It's just to let them know. I think this is more of a notification e-mail.

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Q. It's to tell, for example, you, Dr. Kathe Sackler, Dr. Richard Sackler, this is a standard meeting that you can come to that you need to be aware of, fair?

MR. SNAPP: Object to the form.

THE WITNESS: So as long ago as this was, I'm not exactly sure, you know, why, you know, everyone was on here, but that does occur, as you described.

BY MR. STEWART:

Q. I mean, what you do know is they were all invited to this particular recurring meeting?

MR. SNAPP: Object to the form.

THE WITNESS: All I know is they were notified about this particular meeting.

BY MR. STEWART:

Q. Okay. Why don't you turn to the next page. Do you see you have a document in front of you marked 8153?

A. Yes.

Q. Okay. Now, is this an e-mail

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from Joyce Mulligan sending around a report?

A. That's what it says in the body of the e-mail.

Q. Sending around something called a Regulatory Agency Contact Report?

A. Correct.

Q. What's that?

A. We refer to it as a RACR. Any time that there is a conversation with FDA, a phone call, an e-mail, as we talked about earlier, we might relate it to those information requests, we might get an e-mail from FDA rather than a paper. We don't do anything with paper anymore. An e-mail with an attachment, for instance, any time those occur they are sent -- they are recorded as a contact report, and over the years it's been in different forms.

Q. The point is --

A. So that it's -- so that it's part of the record.

Q. -- when there's an FDA contact, a report is sent around so everybody knows about it that might have interest in it or need to know; is that fair?

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A. That's fair.

MR. SNAPP: Object to the form.

BY MR. STEWART:

Q. Now, do you see here that in addition to you, Dr. Kathe Sackler and Dr. Richard Sackler got this RACR report?

MR. SNAPP: Object to the form.

BY MR. STEWART:

Q. It's the third line up from the bottom.

MR. SNAPP: Beyond the scope.

THE WITNESS: I see them on there, yes.

BY MR. STEWART:

Q. Do you know one way or the other whether that's typical for them to get all the RACR reports?

MR. SNAPP: Object to form, beyond the scope.

THE WITNESS: I believe it's not typical for them to get all the RACR reports.

BY MR. STEWART:

Q. Why do you believe that?

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A. Well, I can tell you since I've been head of regulatory, I have not sent them to -- I should be careful. Board members. The only time that I communicate -- there have been times I communicated to the board, the entire board, and those would be events such as a drug approval, you know, so -- so for me directly, it would be announcement of something major.

Q. In 2002 in the e-mail that is Bates Number 8513 was sent, who is Joyce Mulligan? What did she do?

A. She was an administrative assistant, but I'm not sure who -- I know -- I believe she was in regulatory affairs at the time -- oh, and here it is, sorry.

If you look at the -- who distributed this at the bottom, it's Chris Prue, so he's -- Joyce was his administrative assistant.

Q. You see you have another document, it's a very lengthy document that starts at Bates stamp 1419 and ends at Bates stamp 1421.

A. Yes.

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Q. I won't make you find your name on here, but tell me is this a -- tell me what this e-mail is designed to do?

MR. SNAPP: Object to the form.

THE WITNESS: So I don't have the attachment that it's talking about. It looks like it's a calendar of the R&D -- international R&D meetings to inform people when they are.

BY MR. STEWART:

Q. Okay. So this is just a calendar that tells everyone when they can go to these meetings, fair?

MR. SNAPP: Object to the form.

THE WITNESS: It's not inviting them to the meeting, it's just showing them when they occur providing further information.

BY MR. STEWART:

Q. Turn to the last page in this group. It's 8174.

Do you see that?

A. Yes, sorry.

Q. Do you see it's a distribution,

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e-mail distributing a January 2002 letter from the FDA?

A. Yep, yes.

Q. And it's a letter approving the labeling supplement for the OxyContin patient package insert?

A. Yes, that's what it says.

Q. Here again, I notice that in addition to you, Dr. Kathe Sackler and Dr. Richard Sackler are copied.

Do you see that?

MR. SNAPP: Object to the form.

BY MR. STEWART:

Q. Second line up.

MR. SNAPP: Beyond the scope.

THE WITNESS: I see that, yes.

BY MR. STEWART:

Q. Why were they receiving a routine correspondence from the FDA?

MR. SNAPP: Object to the form, beyond the scope.

THE WITNESS: This is more than -- similar to what I mentioned before, approvals of regulatory

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submissions have a wider distribution.

BY MR. STEWART:

Q. And to figure out what Dr. Richard Sackler was involved in, we just have to -- we'd have to look at all the various calendar entries and all the e-mails, fair?

MR. SNAPP: Object to the form, object as beyond the scope.

THE WITNESS: I have no knowledge of how to -- of that.

BY MR. STEWART:

Q. You can speak to these e-mails because you're on them, right?

A. You've shown them to me, so I can speak to that they are -- they are listed on there.

Q. Now, let me ask you something. Have you ever had a conversation outside of a board meeting with Dr. Richard Sackler?

MR. SNAPP: Object to the form, objection as beyond the scope.

THE WITNESS: Very rare. In the hallway. One I remember particularly, I'm a Type I diabetic with an insulin

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pump, and Purdue was looking at an inhaled insulin product, and Dr. Sackler wanted to talk to me about it.
BY MR. STEWART:
Q. Do you remember any conversations with Dr. Sackler about regulatory matters?
MR. SNAPP: Objection as beyond the scope.
THE WITNESS: Not that I remember.
BY MR. STEWART:
Q. How often would Dr. Sackler contact you with respect to an issue involving the safety of a Purdue product?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: I have never had a conversation with Dr. Sackler about that. I wasn't head of regulatory until 2014, but, personally, I haven't had a conversation about that.
MR. STEWART: It's our last exhibit.
(Document marked for

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identification as Exhibit Purdue-Fanelli-58.)
THE WITNESS: This looks -- oh, it's different.
MR. SNAPP: Wait for a question.
BY MR. STEWART:
Q. Do you have in front of you Exhibit 58, sir?
A. Yes, I do.
Q. And do you see or do you recognize the document?
A. I have a vague recollection of it. I'd have to look through it more carefully.
Q. Well, it's a filing that you provided to the Food and Drug Administration, right?
A. Mm-hmm.
Q. Okay. Why don't you look at it, and then I'll ask you some questions.
A. Sure. (Witness reviews document.) Okay.
Q. Do you remember filing this?
A. Vaguely, yes.
Q. Okay. Why vaguely? It seems

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like a pretty extensive document.
A. I don't remember all the details.
Q. Okay.
A. But I remember it.
Q. Again, I take it this is a filing with the FDA, so your intention would have been to provide truthful information to the regulator, fair?
A. Yes.
Q. Okay. Do you see on the second page which is Bates stamped 6540, the first complete sentence states, "This suggests that the relationship between prescribed opioid dose and the risk of opioid overdose is complex and requires more careful scientific investigation."
Do you see that?
A. Yes.
Q. That's Purdue's understanding as we -- at least as of 2013 of the relationship between dose and the complication of overdose?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: That's what's stated there, yes.

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BY MR. STEWART:
Q. Okay. And this would have all -- this material, because it's provided to the FDA, this would have been subject to the review process that you're here to discuss today as a corporate representative?
A. As we discussed, this is actually the part of a series, and we've discussed similarly on that other document, yes.
Q. So if somebody, Purdue or anyone else, has said in the past that increasing the dose of opioids doesn't increase a risk of overdose, that wouldn't be consistent with Purdue's understanding; is that fair?
MR. SNAPP: Object to the form. Objection as beyond the scope.
THE WITNESS: So like I mentioned before, science around all of -- all of the risks is continuing to evolve. So at this time this -- that's a statement related to this document.
BY MR. STEWART:
Q. And could you remind us who the human being is that could best describe the

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evolution of Purdue's understanding of the relationship between prescribed opioid dose and the risk of overdose over time has been?

MR. SNAPP: Objection, beyond the scope and form.

THE WITNESS: Again, it's changed over time, the department. The author here Paul Coplan was head of the group of our epidemiological scientists at this current time, and they reside in the medical affairs group, the ones that we've been talking about prior, not research and development but medical affairs.

MR. STEWART: Let's take a two-minute break, and then we'll be about done.

THE VIDEOGRAPHER: Stand by, please. The time is 5:19 p.m., going off the record.

(Brief recess.)

THE VIDEOGRAPHER: We are back on the record. The time is 5:22 p.m.

BY MR. STEWART:

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Q. Dr. Fanelli, you talked about a number of systems Purdue uses to, among other things, measure diversion.

Do you remember that?

A. Yes.

Q. Is the Navippro, N-a-v-i-p-p-r-o, system one of those?

MR. SNAPP: Objection, beyond the scope.

THE WITNESS: Yes.

BY MR. STEWART:

Q. And can you just tell me what your understanding of Navippro is?

MR. SNAPP: Objection, beyond the scope.

THE WITNESS: Without seeing the protocol, I know it's one of the systems used, but I'm not -- it's not part of my expertise without seeing the protocol.

BY MR. STEWART:

Q. You'd have to have the protocol in front of you, and then you could speak to it?

A. I would know more about what we're talking about.

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Q. And that's -- I mean, it's part of -- the Navippro is one of the systems that informs some of your filings with the Food and Drug Administration, fair?

MR. SNAPP: Objection, beyond the scope.

THE WITNESS: There's protocols related to that that have been submitted to the FDA, yes.

(Document marked for identification as Exhibit Purdue-Fanelli-59.)

BY MR. STEWART:

Q. By the way, do you happen to know if Navippro -- if in Navippro it includes information about where patients got the drugs that they're abusing?

MR. SNAPP: Objection, beyond the scope.

THE WITNESS: Without the information about it, I would not know or don't know.

BY MR. STEWART:

Q. We'd have to look at the

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protocol?

A. Yeah.

Q. I've got a document I've just handed you, and it's Exhibit 59.

Do you see that?

A. Yes.

Q. Okay. Do you see it's an e-mail from you to Raul Damas?

A. Yes.

Q. And you're going back and forth, and what you've got is a -- you're commenting on a comment by a David Haddox?

A. I'm not -- I'm just forwarding it. I don't see my comment.

Q. Okay. Well, you're forwarding this, these materials with David Haddox's comment, right?

A. So, yes, I forwarded along an e-mail that I received from David Haddox along with other individuals on to Raul Damas.

Q. Who is David Haddox?

A. Currently, he was head of our health policy department, I believe.

Q. What was his -- how did you

interact with David Haddox in your work?
A. So and this is an example, if you start -- the first e-mail from -- is a list of an advisory committee and a science board meeting. Again, I don't remember the details of this, but health policy, David might be -- provide comments. He probably watched the advisory committee, and he provided that comment, but I don't know. I can't remember specifically. So we might -- as regulatory if -- especially advisory committees, we talked about the playbook that falls under regulatory in terms of monitoring and so forth, so that's probably what that was about.
Q. What is Haddox -- what is Dr. Haddox commenting on here with his comment in this e-mail that's the Exhibit 59 in front of you?
MR. SNAPP: Object to the form.
THE WITNESS: First of all, I don't -- without seeing the entire materials for the advisory committee, I don't know what question two was so -- and it's -- I don't recall the details

around this.
BY MR. STEWART:
Q. But you say that what Haddox takes issue is is this concept of "growing epidemic of opioid abuse" and his comment is "perhaps looking at the data instead of parroting histrionic media and politicians might be a good place to start toward improving our understanding of the abuse of drugs used to treat pain."
A. I see that.
Q. I mean, his view is that if you talk about a growing epidemic of opioid abuse, then you're parroting histrionic media and politicians?
MR. SNAPP: Object to the form.
THE WITNESS: I don't know what Dr. Haddox's intentions were, just reading this.
BY MR. STEWART:
Q. You just took his e-mail and forwarded it then?
MR. SNAPP: Object to the form.
THE WITNESS: So I don't recall

the situation around this.
BY MR. STEWART:
Q. You're not disputing the fact he sent that e-mail, fair?
A. Correct.
Q. You just -- and I guess what you did is you took his comment and you forwarded it to Raul Damas, correct?
A. Yes, I did.
Q. And then he said, I saw it, thanks. I think this is best handled by others?
A. Correct.
Q. And you don't know what was done with Dr. Haddox's view about parroting histrionic media and politicians?
MR. SNAPP: Objection, beyond the scope.
THE WITNESS: I do not know after that.
MR. STEWART: That's all I've got. Thank you.
MR. SNAPP: For the record, we are adjourned until tomorrow morning when you're going to cover topic 29.

MS. DICKINSON: Yes.
MR. SNAPP: And then we'll go off the record and restart as his fact deposition. Would that be the plan on your side?
MS. DICKINSON: That's the plan.
MS. POLLOCK: Are you going to be asking questions?
MR. SNAPP: I will ask questions, thank you. Yes, I will ask questions, some follow-up questions after you all are done with topic 29, and then we can close the record whenever. Thank you.
THE VIDEOGRAPHER: All right. Standby. The time is 5:29 p.m., going off the record.
(Witness excused.)
– – –

C E R T I F I C A T I O N

I, MARGARET M. REIHL, a Registered Professional Reporter, Certified Realtime Reporter, Certified Shorthand Reporter, Certified LiveNote Reporter and Notary Public, do hereby certify that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place, and on the date hereinbefore set forth.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

Margaret M. Reihl, RPR, CRR, CLR
CSR #XI01497 Notary Public

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ACKNOWLEDGMENT OF DEPONENT

I, RICHARD J. FANELLI, Ph.D., do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

RICHARD J. FANELLI, Ph.D. DATE

Subscribed and sworn to before me this

_____ day of _____, 2018.

My commission expires:_____

_____

Notary Public